# EXHIBIT "B"

**Mark S. Karpo**
State Bar No.: 70531
**Mark S. Karpo, P.C.**
137 N. 9th St.
Philadelphia, PA 19107-2410
(215) 923-6364
(215) 923-6341
**Arnold & Itkin LLP**
**Kurt B. Arnold**
Texas State Bar No.: 24032461
*Pro Hac Vice Pending*
**Michael E. Pierce**
Texas State Bar No.: 24039117
*Pro Hac Vice Pending*
1401 McKinney St., Suite 2550
Houston, TX 77010
(713)222-3800
(713)222-3850 - Fax

***Attorneys for Plaintiffs***



| | | |
|---|---|---|
| **Robert Porter and Katherine Porter, Individually and as Parents and Natural Guardians of Robert T. "Bo" Porter, A Minor,** | § | **COURT OF COMMON PLEAS TRIAL DIVISION PHILADELPHIA COUNTY** |
| **Plaintiffs,** | § | **September Term 2007** |
| **vs.** | § | **NO.: 003275** |
| **SmithKline Beecham Corporation d/b/a, GlaxoSmithKline,** | § | **IN RE: PAXIL-PREGNANCY** |
| **Defendant.** | § | **JURY TRIAL DEMAND** |

**CIVIL ACTION SHORT - FORM COMPLAINT FOR PAXIL PREGNANCY CASES**

Pursuant to the Order by the Honorable Paul P. Panepinto, Philadelphia County Court of Common Pleas, the following Short Form Complaint is utilized in this mass tort action for cases alleging that a child suffers from a congenital birth defect, from Persistent Pulmonary Hypertension of the Newborn ("PPHN"), or other related or similar conditions, as a result of the child's mother

ingesting the prescription medication Paxil, Paxil OS or Paxil CR ("Paxil") during her pregnancy (hereinafter "Paxil Pregnancy Cases"). Plaintiffs select and indicate the causes of action raised in their case by checking off the appropriate spaces corresponding to the causes listed herein. In the event that a cause not listed herein is being raised, or where a claim requires, pursuant to Pennsylvania law, specific pleading or case-specific facts, Plaintiff(s) shall add and include said cause or said pleading or facts by way of submitting a Supplemental Short Form Complaint as approved by the Court's Case Management Order.

1. Robert T. Porter, child, a minor, by Katherine Porter and/or Robert Porter, Parents and Guardians, against GlaxoSmithKline "GSK."

2. A. Minor Plaintiff / Decedent

Name:

Robert T. Porter

Place of Birth:

Peoria, IL

State of Residence:

IL

Date of Birth:

03/02/2006

Date of Death:

N/A

B. Guardian for Minor Plaintiff:

Name:

Katherine Porter and Robert Porter

State of Residence:

IL

Relationship to Minor Plaintiff:

Mother and Father

C. Mother of Minor Plaintiff, Individually:

Name:

Katherine Porter

State of Residence:

IL

D. Father of Minor Plaintiff, Individually:

Name:

Robert Porter

State of Residence:

IL

E. Wrongful Death Beneficiaries and/or Personal Representative of Estate of:

N/A

Name:

N/A

State of Residence:

N/A

Name:

N/A

State of Residence:

N/A

3. Robert T. Porter's mother ingested the following drugs relevant to this action for the described period:

Paxil Oral Suspension _____

Dose (if known): 25 mg

4. The prescribing physician was:

Dr. Sunny Lee, M.D.

5. Robert T. Porter was born with or developed the following condition:

Congenital Heart Defect; Congenital Birth Defect, PPHN

6. Katherine Porter and Robert Porter, individuals residing in the state noted above and claim damages as a result of Robert T. Porter's mother's ingestion of Paxil during her pregnancy.

7. The following claims are asserted herein:

| | | |
|---|---|---|
| X | Count One: | Breach of Express Warranty |
| X | Count Two: | Breach of Implied Warranty |
| X | Count Three: | Fraud |
| X | Count Four: | Intentional Infliction of Emotional Distress |
| X | Count Five: | Loss of Consortium |
| X | Count Six: | Negligence |
| X | Count Seven: | Negligence Per Se |
| X | Count Eight: | Negligent Pharmacolvigilance |
| X | Count Nine: | Failure to Warn |
| X | Count Ten: | Negligent Misrepresentation |
| X | Count Eleven: | Punitive Damages |
| X | Count Twelve: | Strict Products Liability |
| N/A | Count Thirteen: | Survival/Survivorship Action |
| X | Count Fourteen: | Violation of Consumer Act |
| N/A | Count Fifteen: | Wrongful Death |

| | | |
|---|---|---|
| X | Count Sixteen: | Loss of Income |
| X | Count Seventeen: | Medical Expenses |
| X | Count Eighteen: | Design Defect |

DATED: November 15, 2007

Respectfully Submitted,

**Mark S. Karpo**
State Bar No.: 70531
**Mark S. Karpo, P.C.**
137 N. 9th St.
Philadelphia, PA 19107-2410
(215) 923-6364
(215) 923-6341

**Arnold & Itkin LLP**
**Kurt B. Arnold**
Texas State Bar No.: 24032461
*Pro Hac Vice Pending*
**Michael E. Pierce**
Texas State Bar No.: 24039117
*Pro Hac Vice Pending*
1401 McKinney St., Suite 2550
Houston, TX 77010
(713)222-3800
(713)222-3850 - Fax

***Attorneys for Plaintiffs***

**CERTIFICATE OF SERVICE**

I, Mark S. Karpo, of the law firm Mark S. Karpo, P.C., hereby certify that a true and correct copy of the foregoing Short Form Complaint, was filed with the Prothonotary of the Philadelphia Court of Commons Pleas and mailed by U.S. mail postage pre-paid, this 19 day of November, 2007, to all counsel of record as noted below.

**Lavin, O'Neil, Ricci, Cedrone & DiSipio**
Joseph E. O'Neil
Mary Grace Maley

Carolyn L. McCormack
137 N. 9th Street
Philadelphia, PA 19107

***Counsel for Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline***

MARK S. KARPO

By:_____
Mark S. Karpo
***Attorney for Plaintiffs***

**VERIFICATION**

I, Robert Porter, hereby state that I am a plaintiff in the within action, and the parent and guardian of Robert, who is also a plaintiff in the within action. I hereby state the facts set forth in the foregoing Plaintiffs' Complaint are true and correct to the best of my knowledge, information and belief. I understand that this Verification is being made subject to 18Pa. C.S. § 4904 related to unsworn falsification to authorities.

DATE: September 28, 2007 SIGNATURE: _____

PRINT NAME: Robert Porter

**VERIFICATION**

I, Katherine Porter, hereby state that I am a plaintiff in the within action, and the parent and guardian of Robert, who is also a plaintiff in the within action. I hereby state the facts set forth in the foregoing Plaintiffs' Complaint are true and correct to the best of my knowledge, information and belief. I understand that this Verification is being made subject to 18Pa. C.S. § 4904 related to unsworn falsification to authorities.

DATE: September 28, 2007 SIGNATURE: Katherine Porter

PRINT NAME: Katherine Porter

# EXHIBIT "C"

**Rosemary Pinto, Esquire**
PA Bar #53114
**FELDMAN & PINTO**
1604 Locust Street, 2nd Floor
Philadelphia, PA 19103
Tel: 215-546-2604
Fax: 215-546-9904

**ARNOLD & ITKIN LLP**
**Kurt B. Arnold, Esquire**
**Jason A. Itkin, Esquire**
Texas State Bar No.: 24039117
1401 McKinney St., Suite 2550
Houston, Texas 77010
Tel: 713-222-3800
Fax: 713-222-3850
***Attorneys for Plaintiff***

**This is Not An Arbitration Case. An Assessment of Damages Is Required.**

| | |
|---|---|
| **ROBERT PORTER and KATHERINE PORTER, Individually, and as Parents and Natural Guardians of ROBERT T. "Bo" PORTER, A Minor**<br>1160 ROCKWELL<br>XENIA, OH 45385<br><br>**Plaintiffs,**<br><br>vs.<br><br>**SMITHKLINE BEECHAM CORPORATION D/B/A, GLAXOSMITHKLINE,**<br>ONE FRANKLIN PLAZA<br>PHILADELPHIA, PA 19102-1225<br><br>And<br><br>**PFIZER, INC.,**<br>CT Corporation System<br>116 Pine Street, Suite 320<br>Harrisburg, PA 17101<br><br>**Defendants.** | **COURT OF COMMON PLEAS**<br>**TRIAL DIVISION**<br>**PHILADELPHIA COUNTY**<br><br>**SEPTEMBER 2007 TERM**<br><br>**NO. : 070903266**<br><br>**IN RE: PAXIL PREGNANCY CASES**<br><br>**JURY TRIAL DEMANDED** |

## CIVIL ACTION FIRST AMENDED SHORT - FORM COMPLAINT

Case ID: 070903275
Control No.: 12050436
SC0112

**FOR PAXIL PREGNANCY CASES**

Pursuant to the Order by the Honorable Allan L. Tereshko, Philadelphia County Court of Common Pleas, the following Short Form Complaint and Supplemental Short Form are utilized in this mass tort action for cases alleging that a child suffers from a congenital birth defect, from Persistent Pulmonary Hypertension of the Newborn ("PPHN"), or other related or similar conditions, as a result of the child's mother ingesting the prescription medication Paxil, Paxil OS or Paxil CR ("Paxil") and/or Zoloft (sertraline hydrochloride) ("Zoloft") during her pregnancy. Plaintiff(s) select(s) and indicate(s) the causes of action raised in his/her/their case by checking off the appropriate spaces corresponding to the causes listed herein. In the event that a cause not listed herein is being raised, or where a claim requires, pursuant to Pennsylvania law, specific pleading or case-specific facts, Plaintiff(s) shall add and include said cause or said pleading or facts by way of submitting a Supplemental Short Form Complaint as approved by the Court's Case Management Order.

1. Robert T. Porter, child, a minor, by Katherine Porter and/or, Parent and Guardian, against SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK").

2. A. Minor Plaintiff / Decedent

| | |
|---|---|
| Name: | Robert T. Porter |
| Place of Birth | Peoria, IL |
| State of Residence: | Ohio |
| Date of Birth: | 03/06/2006 |
| Date of Death: | N/A |

B. Guardians for Minor Plaintiff:

| | |
|---|---|
| Name: | Katherine Porter and Robert Porter |
| State of Residence: | Ohio |
| Relationship to | |

Minor Plaintiff: Mother and Father of Injured Child

C. Mother of Minor Plaintiff, Individually:
Name: Katherine Porter
State of Residence: Ohio

D. Father of Minor Plaintiff, Individually:
Name: Robert Porter
State of Residence: Ohio

E. Wrongful Death Beneficiaries and/or Personal Representative of Estate of Joey L. Davis, Minor Plaintiff.
Name: N/A
State of Residence: N/A
Name: N/A
State of Residence: N/A

3. Robert T. Porter's mother ingested the following drugs relevant to this action for the described period:

| | |
|---|---|
| Paxil | X |
| Dose (if known): | 25 mg |
| Zoloft | X |
| Dose (if known): | 50 mg |

4. The prescribing physician was: Sunny Lee, M.D.

5. Robert T. Porter was born with or developed the following condition(s): Omphalocele, PPHN, and other related injuries.

6. Katherine Porter and Robert Porter, an individuals residing in the state noted above and claim damages as a result of Robert T. Porter's mother's ingestion of Paxil and/or Zoloft during her pregnancy.

7. The following claims are asserted herein:

| | | |
|---|---|---|
| X | Count One: | Breach of Express Warranty |
| X | Count Two: | Breach of Implied Warranty |

| | | |
|---|---|---|
| X | Count Three: | Fraud |
| X | Count Four: | Intentional Infliction of Emotional Distress |
| X | Count Five: | Loss of Consortium |
| X | Count Six: | Negligence |
| X | Count Seven: | Negligence Per Se |
| X | Count Eight: | Negligent Pharmacovigilance |
| X | Count Nine: | Failure to Warn |
| X | Count Ten: | Negligent Misrepresentation |
| X | Count Eleven: | Punitive Damages |
| X | Count Twelve: | Strict Products Liability |
| N/A | Count Thirteen: | Survival/Survivorship Action |
| X | Count Fourteen: | Violation of Consumer Act |
| N/A | Count Fifteen: | Wrongful Death |
| X | Count Sixteen: | Loss of Income |
| X | Count Seventeen: | Medical Expenses |
| X | Count Eighteen: | Design Defect |

**DATED: May 3, 2012**

Respectfully submitted,

**ARNOLD & ITKIN LLP**

BY: /s/

**Kurt B. Arnold, Esquire**
**Jason A. Itkin, Esquire**
1401 McKinney Street, Ste 2550
Houston, Texas 77010
Telephone: 713-222-3800
Telecopier: 713-222-3850

Rosemary Pinto, Esquire
PA Bar #53114
Feldman & Pinto
1604 Locust Street, 2nd Floor
Philadelphia, PA 19103

Telephone: 215-546-2604
Telecopier: 215-546-9904
**ATTORNEYS FOR PLAINTIFFS**

**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the above and foregoing instrument has been forwarded to counsel of record, by the undersigned, pursuant to Pennsylvania Rules of Civil Procedure on the 3rd day of May, 2012.

Joseph E. O'Neil, Esquire
Carolyn McCormack, Esquire
Mary Grace Maley, Esquire
Lavin, O'Neil, Ricci, Cedrone & DiSipio
190 North Independence Mall West
6th & Race Streets
Philadelphia, PA 19106
Counsel for Defendants

/s/
Jason A. Itkin

**Rosemary Pinto, Esquire**
PA Bar #53114
**FELDMAN & PINTO**
1604 Locust Street, 2nd Floor
Philadelphia, PA 19103
Tel: 215-546-2604
Fax: 215-546-9904

**ARNOLD & ITKIN LLP**
**Kurt B. Arnold, Esquire**
**Jason A. Itkin, Esquire**
Texas State Bar No.: 24039117
1401 McKinney St., Suite 2550
Houston, Texas 77010
Tel: 713-222-3800
Fax: 713-222-3850
***Attorneys for Plaintiff***

**This is Not An Arbitration Case. An Assessment of Damages Is Required.**

| | |
|---|---|
| **ROBERT PORTER and KATHERINE PORTER, Individually, and as Parents and Natural Guardians of ROBERT T. "Bo" PORTER, A Minor** | **COURT OF COMMON PLEAS**<br>**TRIAL DIVISION**<br>**PHILADELPHIA COUNTY** |
| **Plaintiffs,** | **SEPTEMBER 2007 TERM**<br>**NO. : 070903266** |
| vs. | **IN RE: PAXIL PREGNANCY CASES** |
| **SMITHKLINE BEECHAM CORPORATION D/B/A, GLAXOSMITHKLINE,** | |
| and | **JURY TRIAL DEMANDED** |
| **PFIZER, INC.,** | |
| **Defendants.** | |

**SUPPLEMENT TO FIRST AMENDED SHORT–FORM COMPLAINT FOR PAXIL PREGNANCY CASES**

8. Pursuant to the Orders by the Honorable Allan L. Tereshko, Philadelphia County Court of Common Pleas, Plaintiff files the following Supplement to Short Form Complaint:

**INCORPORATION OF SHORT-FORM AND LONG-FORM COMPLAINTS**

9. Plaintiffs' paragraphs 1 through 7 (Short-Form Complaint, and amendments or supplements thereto) and the approved Long-Form Complaint are incorporated herein as if set forth in full.

**DEFENDANTS**

10. Plaintiffs incorporate by reference all the above referenced paragraphs as if set forth in full herein.

11. Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK") was and still is a corporation duly existing under and by virtue of the laws of the State of Pennsylvania with its principal place of business in Philadelphia, Pennsylvania. At all times hereinafter mentioned, GSK was, and still is, a pharmaceutical company involved in research, development, testing, manufacturing, production, promotion, distribution, and marketing of pharmaceuticals for distribution, sale, and use by the general public, including the drug Paxil (known generically as Paroxetine), an antidepressant, throughout the United States.

12. Defendant, Pfizer, Inc. ("Pfizer") was and still is a corporation duly existing under and by virtue of the laws of the State of Delaware with its principal place of business in the New York City, New York. Pfizer may be served with process by serving its registered agent: CT Corporation, 116 Pine Street, Suite 320, Harrisburg, PA 17101. At all

times hereinafter mentioned, Pfizer was, and still is, a pharmaceutical company involved in research, development, testing, manufacturing, production, promotion, distribution, and marketing of pharmaceuticals for distribution, sale, and use by the general public, including the drug Zoloft (sertraline hydrochloride) ("Zoloft") an antidepressant, throughout the United States.

**JURISDICTIONAL ALLEGATIONS**

13. Plaintiffs incorporate by reference all the above referenced paragraphs as if set forth in full herein.

14. Jurisdiction is proper because GSK is a Pennsylvania corporation. Venue is proper in this District Because GSK resides in this county for venue purposes and a substantial part of the events and omissions giving rise to Plaintiff's injuries occurred in this District. *See* Pa. R. C.P. 2179, as amended by 2003 Pennsylvania Court Order 8.

15. At all times material to this action, Defendant Pfizer and/or its predecessors in interest and/or its subsidiaries, regularly engaged in business in the Commonwealth of Pennsylvania and the County of Philadelphia, including advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packing, producing, promoting, processing, researching, selling, and testing of the pharmaceutical drug Zoloft. Defendant Pfizer carried on a continuous and systematic part of their business in Pennsylvania and in Philadelphia County. Furthermore, as Defendant Pfizer regularly solicited and transacted business, received substantial revenues from the Commonwealth of Pennsylvania, and/or distributed products in the Commonwealth of Pennsylvania and the City of Philadelphia, Defendant Pfizer is subject to suit in the Commonwealth of Pennsylvania. In addition, Defendant Pfizer

reasonably expected that Zoloft would be used or consumed in Pennsylvania and Philadelphia County. Furthermore, a part of the events and omissions giving rise to Plaintiffs' injuries occurred in this District.

16. This is an action for damages that exceed the sum of fifty thousand dollars ($50,000.00).

17. Plaintiffs have timely filed this lawsuit within the applicable statutory limitations period.

18. **No Basis for Removal.** There is no basis for removal of this case to federal court. Plaintiffs are not asserting a claim or right arising under the Constitution, treaties, or laws of the United States, thus, there is no federal question at issue pursuant to 28 U.S.C.§1441(b) and 28 U.S.C. §1331. There is no complete diversity of citizenship pursuant to 28 U.S.C. §1441(b) and 28 U.S.C. §1332(c), because GSK is a citizen of the Commonwealth of Pennsylvania. *See also Slater v. Hoffman-La Roche Inc.*, 771 F.Supp.2d 524 (E.D. Pa. 2011). Moreover, removal pursuant to 28 U.S.C. § 1332 upon the filing of a subsequent amended pleading more than one year after the filing of an initial pleading commencing the case, is expressly forbidden by the plain language of 28 U.S.C. § 1446(b). (*See* also, *Donato-Cook v. State Farm Fire & Cas. Co.*, CIV A 3:09-CV-0587, 2009 WL 2169168 (M.D. Pa. July 20, 2009)) (Defendant's notice of removal is time-barred by the one-year exception to removal in diversity cases pursuant to 28 U.S.C. § 1446(b).)

19. This matter was commenced more than one year ago, complete diversity is lacking and there is no federal question at issue. Any attempt to remove this matter would be improper and would provide grounds for sanctions.

## GENERAL ALLEGATIONS

20. Plaintiff incorporates by reference all the above paragraphs as if set forth in full herein.

21. The Mother Plaintiff took Zoloft as prescribed by her treating physician(s) while pregnant with Infant Plaintiff. The Mother Plaintiff continued to use Zoloft on the schedule and for the period of time prescribed by the Mother Plaintiff's physician(s).

22. The Mother Plaintiff took Zoloft as prescribed by her treating physician(s) while pregnant with the Infant Plaintiff. The Mother Plaintiff continued to use Zoloft on the schedule and for the period of time prescribed by the Mother Plaintiff's physician(s).

23. The Mother Plaintiff read the drug information and instructions that accompanied the Zoloft prescription prior to her taking Zoloft. The Mother Plaintiff trusted that serious conditions associated with Zoloft, such as congenital birth defects, would have been included and emphasized in the written drug information provided to her with her prescription. The Mother Plaintiff relied upon the fact that congenital birth defects and other serious pregnancy issues were not listed or emphasized on the Zoloft monograph and/or drug information as a basis to believe that Zoloft was safe for use during her pregnancy and would not cause congenital birth defects.

24. Despite the exercise of reasonable diligence in investigating the cause of the injuries, including consultations with her medical care providers, the Mother Plaintiff was not told that Zoloft could have caused the Infant Plaintiff's injuries. Nor did the Mother

Plaintiff see or read any information suggesting Zoloft caused the Infant Plaintiff's injuries until a date within the applicable statute of limitations for filing Plaintiffs' claims.

25. Had the Mother Plaintiff been adequately warned that Zoloft could cause congenital birth defects if ingested during pregnancy, she would not have taken the drug

26. When the Infant Plaintiff was born, he was suffering from life-threatening congenital defects.

27. The defects suffered by the Infant Plaintiff were a direct result of his mother's ingestion of Zoloft during her pregnancy in a manner and dosage recommended and prescribed by her doctor.

28. The drug "sertraline hydrochloride" was and is advertised, analyzed, assembled, compounded, designed, developed, distributed, formulated, inspected, labeled, manufactured, marketed, packed, produced, promoted, processed, researched, sold, and tested by Pfizer, its predecessors in interest and its subsidiaries, under the trade name Zoloft ® and is a member of a class of drugs known as "selective serotonin reuptake inhibitors" or "SSRIs." Zoloft was first approved for use in the United States by the FDA in 1991 for the treatment of major depression in adults.

29. Under the FDA scheme, Pfizer, knew, as a New Drug Application applicant, that it must fully, truthfully and accurately disclose to the FDA data and information regarding a new drug's chemistry, proposed manufacturing process, proposed model labeling which includes warnings about risks and side effects, test results for the drug, results of animal studies, results of clinical studies and the drug's bioavailability, because the data and information would be relied upon by the medical community, physicians, Plaintiffs'

physicians, Plaintiffs and other foreseeable prescribers and users of Zoloft once the NDA was approved.

30. Under the FDA scheme, Pfizer had a duty to ensure its warnings to the medical community are and remain accurate and adequate, to conduct safety surveillance of adverse events for the drug, to report *any* data related to the safety and/or accuracy of the warnings and information disseminated regarding the drug, and to update the label when new safety information was obtained.

31. Prior to the Mother Plaintiff becoming pregnant, Pfizer knew or should have known that taking Zoloft during pregnancy posed risks to the developing fetus. Pfizer knew or should have known that Zoloft crosses the placenta, which could have important implications for the developing fetus.

32. Prior to the Mother Plaintiff becoming pregnant, Pfizer knew or should have known that children were being born with congenital birth defects, heart defects, PPHN, omphalocele and other similar conditions to women who took Zoloft during pregnancy.

33. Prior to the time that the Mother Plaintiff ingested Zoloft during her pregnancy, Pfizer knew of the dangerous birth defects associated with Zoloft's use during pregnancy from the preclinical studies and the subsequent published studies confirming these risks. Pfizer took no action to adequately warn or remedy the risks, but instead concealed, suppressed, and failed to disclose the dangers. Even in the face of the numerous published studies, Pfizer continues to fail to warn of these dangers through revised drug labeling.

34. Pfizer had access to this information and knew that congenital birth defects would result from the use of Zoloft by women who became pregnant and the fact that

physicians and the consumers such as the Mother Plaintiff herein did not fully understand the risks associated with Zoloft.

35. Pfizer failed to fully, truthfully and accurately disclose Zoloft data to the FDA, the Plaintiffs and the Mother Plaintiff's physicians, and as a result negligently, intentionally and fraudulently misled the medical community, physicians, the Mother Plaintiffs' physicians, and Plaintiffs about the risks to a fetus associated with the use of Zoloft during pregnancy.

36. Through the *Physicians' Desk Reference*, drug package inserts, patient information forms, counseling warnings, literature, marketing materials and other labeling information for Zoloft, Pfizer knowingly, intentionally and negligently disseminated incomplete, inaccurate, and/or misleading warnings and information about the true risks to a fetus when Zoloft is ingested during pregnancy, which misled the medical community, physicians and the Mother Plaintiff's physicians.

37. At all times material hereto, Pfizer knew or should have known that most physicians were not aware of or did not fully appreciate the seriousness of the congenital birth defect risks associated with use of Zoloft and that, consequently, there was a widespread tendency for physicians to prescribe Zoloft for use to women of childbearing potential. Consequently, Pfizer knew or should have known that the warnings and labels, including but not limited to, package inserts and the *Physician's Desk Reference* monograph for Zoloft, did not adequately inform physicians about the birth defects risks associated with Zoloft.

38. Pfizer failed to warn physicians and the Mother Plaintiff herein adequately about the congenital birth defect risks associated with Zoloft, despite the fact that Pfizer knew that physicians, the medical community, the Plaintiffs, and others similarly situated relied on Pfizer to disclose what it knew or should have known from a prudent review of the information that it possessed or to which it had access.

39. Because of the misleading information that Pfizer provided to physicians, the Plaintiffs and the FDA about the true congenital birth defect risks associated with the use of Pfizer and because of the failure of Pfizer to adequately inform physicians generally, including the Mother Plaintiff's physicians, about the true birth defect risks associated with the use of Zoloft the Mother Plaintiff's physicians never informed her of any congenital birth defects risks associated with Zoloft. Indeed, it is believed that Pfizer represented to physicians that Zoloft was safe for use by women of childbearing years and their unborn children.

40. Pfizer knew, or should have known, that the warnings, including but not limited to, the label and package insert for Zoloft did not disclose the true risks of birth defects from the use of Zoloft. Pfizer failed to use reasonable care to modify the warnings, including but not limited to, the label and package insert for Zoloft in order to warn physicians adequately about the true congenital birth defect risks from the use of Zoloft by women who became pregnant.

41. During the entire time Zoloft has been on the market in the United States, FDA regulations have required Pfizer to issue stronger warnings whenever there existed reasonable evidence of an association between a serious risk and Zoloft. The regulations

specifically state that a causal link need not have been proven to issue the new warnings. Further, the regulations explicitly allowed Pfizer to issue such a warning without prior FDA approval.

42. Thus, prior to the Mother Plaintiff's pregnancy, Pfizer had the knowledge, the means, and the duty to provide the medical community and the consuming public with a stronger warning regarding the association between Zoloft and congenital birth defects, heart defects, PPHN, and other related conditions, through all means necessary, including, but not limited to, labeling, continuing education, symposiums, posters, sales calls to doctors, advertisements, and promotional materials, etc. Pfizer breached this duty.

43. Despite having extensive knowledge of the extreme risks associated with the Zoloft, as well as the absolute duty to properly and adequately warn foreseeable users, Pfizer never approached the FDA to alter the label for Zoloft so that it properly and adequately warned of the risks of birth defects associated with the drug.

44. Pfizer failed to disclose adequately the increased risk of congenital birth defects of Zoloft to the medical community and the Plaintiffs. Pfizer was aware that its failure to disclose this information to the medical community and the Plaintiffs would result in serious injury and/or death to the children or unborn fetus of women who were prescribed Zoloft by a physician who was not aware of this information. By failing to disclose this information to the medical community and the Plaintiffs, Pfizer acted in willful, wanton and outrageous manner and with evil disregard of the rights of the Plaintiffs and this conduct caused serious and permanent injuries to the Plaintiffs.

45. Pfizer, its agents, servants and employees acting in the course and scope of their employment, negligently and carelessly breached their duties to the medical community, Plaintiffs' physicians, Plaintiffs and other foreseeable users similarly situated, which breaches of duty include, but are not limited to:

a. failing to ensure Zoloft warnings to the medical community, physicians, the Mother Plaintiff's physicians and Plaintiffs were accurate and adequate, despite having extensive knowledge of the risks associated with the drug;

b. failing in its obligation to provide the medical community, physicians, the Mother Plaintiff's physicians, and Plaintiffs with adequate and clinically relevant information, data and warnings regarding the adverse health risks associated with exposure to Zoloft, and/or that there existed safer and more or equally effective alternative drug products;

c. failing to conduct post market safety surveillance and report that information to the medical community, physicians, the Mother Plaintiff's physicians and Plaintiffs;

d. failing to include adequate warnings and/or provide adequate and clinically relevant information and data that would alert the medical community, physicians, Mother Plaintiff's physicians, and Plaintiffs to the dangerous risks of Zoloft;

e. failing to continually monitor, test, and analyze data regarding safety, efficacy and the prescribing practices for Zoloft;

f. failing to review all adverse drug event information (AER) and to report any information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Zoloft to the medical community, physicians, the Mother Plaintiff's physicians, and Plaintiffs;

g. failing to provide adequate post-marketing warnings and instructions after Pfizer knew or should have known of the significant risks of, among other things, congenital birth defects of Zoloft;

h. failing to periodically review all medical literature regarding Zoloft and failing to report data, regardless of the degree of significance, regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Zoloft;

i. failing to disclose the results of the testing and other information in its possession regarding the possibility that Zoloft can interfere with the proper development of an unborn fetus;

j. failing to warn adequately the medical community, physicians, the Mother Plaintiff's physicians, and Plaintiffs of the dangers of using Zoloft during pregnancy, including the risk of congenital birth defects;

k. representing that Zoloft was safe for use during pregnancy when, in fact, Pfizer knew or should have known that it was unsafe for this use and that Zoloft was associated with congenital birth defects;

l. promoting and marketing Zoloft for use with pregnant women, despite the fact that Pfizer knew or should have known that Zoloft was associated with an increased risk of congenital abnormalities;

m. promoting and marketing Zoloft as safe and effective for use with pregnant women when, in fact, it was unsafe;

n. promoting and marketing Zoloft for non-approved (off-label) uses and/or illegally over-promoting, marketing, advertising and selling Zoloft in a zealous and unreasonable way, without regard to the potential danger that it poses for an unborn fetus;

o. failing to independently monitor their sales of Zoloft and the medical literature, which would have alerted them to the fact that Zoloft was widely over-prescribed to women of childbearing potential as a result of inadequate warnings, including those in the package inserts and PDR monographs for Zoloft, and as a result of the over-promotion of the drug;

p. failing to act as a reasonably prudent drug manufacturer in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packing, producing, promoting, processing, researching, selling and testing of Zoloft; and/or

q. failing to perform adequate and necessary studies to determine and analyze the safety and risks associated with Zoloft use.

46. As a direct and proximate result of Pfizer's actions, Plaintiffs, and Mother Plaintiff's prescribing physicians, were unaware, and could not reasonably know, or through reasonable diligence could not have reasonably known, that Zoloft exposed the Plaintiffs to the risks and injuries alleged herein, and that those risks were the direct and proximate result of Pfizer's acts and omissions.

47. As a direct and proximate result of the conduct of Pfizer as described herein and as a result of the Mother Plaintiff's ingestion of Zoloft, the Infant Plaintiff suffers from physical injuries, some or all of which are permanent and/or may be fatal, and the Infant Plaintiff may suffer in the future from other diseases or conditions which have not yet been diagnosed. Further, the Infant Plaintiff has sustained in the past, and will sustain in the future, pain and suffering, mental anguish, embarrassment and humiliation, psychological injury, disability, disfigurement caused by the surgeries and procedures the Infant Plaintiff has already undergone, and the surgeries and procedures that Infant Plaintiff will need to undergo in the future, and the loss of enjoyment of the pleasures of life without the presence of congenital birth defects, and/or other related conditions, as well as past and future general and special damages, including past and future medical care and treatment, lost wages and lost earning capacity.

48. Infant Plaintiff's serious and permanent injuries were the foreseeable and proximate result of Pfizer's acts and/or omissions, including, but not limited to, dissemination of inaccurate, misleading, materially incomplete, false, and otherwise

inadequate information to the medical community, Mother Plaintiff's physicians, pharmacists and Plaintiffs.

49. As a direct and proximate result of the conduct of Pfizer as described herein, Parent Plaintiffs have suffered and will in the future continue to suffer medical, nursing, hospital, pharmacy, rehabilitative and related costs and expenses for the Infant Plaintiff's injuries and care, along with lost wages, lost earning capacity, economic losses, and other damages for which they are entitled to compensation. These injuries and damages were the foreseeable and proximate result of Pfizer's acts and/or omissions, including, but not limited to, dissemination of inaccurate, misleading, materially incomplete, false, and otherwise inadequate information to the medical community, Mother Plaintiff's physicians, pharmacists and Plaintiffs.

50. The Parent Plaintiffs, as result of the Mother Plaintiff's ingestion of Zoloft and as a direct and proximate result of the conduct of Pfizer described herein, have suffered, and will suffer in the future, great emotional pain, mental anguish and other serious injury and loss, including loss of consortium, services, support, companionship, society, love and affection. These injuries and damages were the foreseeable and proximate result of Pfizer's acts and/or omissions, including, but not limited to, dissemination of inaccurate, misleading, materially incomplete, false, and otherwise inadequate information to the medical community, Mother Plaintiff's physicians, pharmacists and Plaintiffs.

51. Pfizer is liable to the Plaintiffs for all general, special and punitive damages, as well as delay damages, and other relief to which they are entitled to by law.

**DISCOVERY RULE, TOLLING AND FRAUDULENT CONCEALMENT**

52. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

53. Plaintiffs assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, fraudulent concealment, and/or minority tolling.

54. Plaintiffs plead that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiffs had been injured, the cause of the injury, and the tortuous nature of the wrongdoing that caused the injury.

55. Despite diligent investigation by Plaintiffs into the cause of their injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages, and their relationship to Zoloft was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiffs' claims. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable statutory limitations period.

56. The running of the statute of limitations in this cause is tolled due to equitable tolling. Pfizer is estopped from asserting a statute of limitations defense due to Pfizer's fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiffs and Plaintiff's physicians and pharmacists of the true risks associated with taking Zoloft. As a result of Pfizer's fraudulent concealment, Plaintiffs and Plaintiff's prescribing

physicians and pharmacists were unaware, and could not have known or have learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of Pfizer.

57. The running of the statute of limitations in this cause may be tolled due to the pendency of a class action proceeding against one or more of the Defendants herein. Class Action tolling is proper where Plaintiffs are members of an asserted class and the claims asserted in the class action proceeding are the same as the claims asserted in this action.

58. The statute of limitations is tolled due to the minority of the Plaintiff. Plaintiff was a minor at the time Plaintiff ingested Zoloft. This action was filed within the applicable statutory period after Plaintiff achieved the age of majority. Ohio Rev. Code Ann. § 2305.16 and § 2305.10.

59. Defendants are estopped from asserting a statute of limitations defense because all Defendants fraudulently concealed from Plaintiffs the nature of Plaintiffs' injury and the connection between the injury and Defendants' tortious conduct.

## CLAIMS FOR RELIEF

60. The Plaintiffs set forth the following statements and claims in the alternative such that the sufficiency of this Complaint shall not be defeated by an inconsistency or insufficiency (if any) among any one or more of the alternative statements or claims.

### COUNT ONE – BREACH OF EXPRESS WARRANTIES
*(As Against Pfizer)*

60. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

61. Pfizer is liable to Plaintiffs under state common law and/or the applicable state Product Liability Acts for the breach of express warranties of Zoloft.

62. At all times hereinafter mentioned, upon information and belief, Pfizer, by directly and indirectly advertising, marketing, and promoting Zoloft for the treatment of women, including women of childbearing potential and pregnant women, and by placing Zoloft in the stream of commerce knowing that Zoloft would be prescribed to pregnant women in reliance upon the representations or omissions of Pfizer, expressly warranted to all foreseeable users of Zoloft, including the Mother Plaintiff and the Mother Plaintiff's physicians, that Zoloft was safe and effective for the treatment of women during pregnancy and without significant risk to the fetus.

63. Pfizer impliedly warranted in manufacturing, distributing, selling, advertising, marketing, and promoting Zoloft to all foreseeable users, including the Mother Plaintiff and the Mother Plaintiff's physicians, that Zoloft was safe and effective for the purposes for which it had been placed in the stream of commerce by Pfizer, including for the treatment of pregnant women, and that Zoloft was reasonably safe, proper, merchantable, and fit for its intended purpose, including for the treatment of pregnant women and without significant risk to the fetus.

64. At all times relevant hereto, Plaintiffs and the Mother Plaintiff's physicians relied upon the aforesaid express warranties by Pfizer.

65. The Mother Plaintiff's use of Zoloft, and the Mother Plaintiff's physicians' prescribing of Zoloft was consistent with the purposes for which Pfizer directly and indirectly advertised, marketed, and promoted Zoloft, and the Mother Plaintiff's use of Zoloft, and the Mother Plaintiff's physicians' prescribing of Zoloft was reasonably contemplated, intended, and foreseen by Pfizer at the time of the distribution and sale of Zoloft by Pfizer, and, therefore, the Mother Plaintiff's use of Zoloft was within the scope of the above-described express warranties.

66. Pfizer breached the aforesaid express warranties because Zoloft was not safe and effective for the treatment of women during pregnancy because it exposed the developing fetus to a significant risk of serious injury, and because the Mother Plaintiff's use of Zoloft for treatment during her pregnancy caused the Infant Plaintiff's injuries.

67. As a direct and proximate result of Pfizer's breach of express warranties, Plaintiffs suffered injuries and damages, as set forth herein.

**WHEREFORE**, for the above reasons, Plaintiffs demand judgment in their favor and against Pfizer for an amount in excess of $50,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

## COUNT TWO - BREACH OF IMPLIED WARRANTIES

*(As Against Pfizer)*

68. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

69. Pfizer is liable to Plaintiffs under state common law and/or the applicable state Product Liability Acts for the breach of implied warranties of Zoloft.

70. At all times hereinafter mentioned, upon information and belief, Pfizer, by directly and indirectly advertising, marketing, and promoting Zoloft for the treatment of women, including women of childbearing potential and pregnant women, and by placing Zoloft in the stream of commerce knowing that Zoloft would be prescribed to pregnant women in reliance upon the representations or omissions of Pfizer, impliedly warranted to all foreseeable users of Zoloft, including the Mother Plaintiff and the Mother Plaintiff's physicians, that Zoloft was safe and effective for the treatment of women during pregnancy and without significant risk to the fetus.

71. Pfizer impliedly warranted in manufacturing, distributing, selling, advertising, marketing, and promoting Zoloft to all foreseeable users, including the Mother Plaintiff and the Mother Plaintiff's physicians, that Zoloft was safe and effective for the purposes for which it had been placed in the stream of commerce by Pfizer, including for the treatment of pregnant women, and that Zoloft was reasonably safe, proper, merchantable, and fit for its intended purpose, including for the treatment of pregnant women and without significant risk to the fetus.

72. At all times relevant hereto, Plaintiffs and the Mother Plaintiff's physicians relied upon the aforesaid implied warranties by Pfizer.

73. The Mother Plaintiff's use of Zoloft, and the Mother Plaintiff's physicians' prescribing of Zoloft was consistent with the purposes for which Pfizer directly and indirectly advertised, marketed, and promoted Zoloft, and the Mother Plaintiff's use of Zoloft, and the Mother Plaintiff's physicians' prescribing of Zoloft was reasonably contemplated, intended, and foreseen by Pfizer at the time of the distribution and sale of Zoloft by Pfizer, and, therefore, the Mother Plaintiff's use of Zoloft was within the scope of the above-described implied warranties.

74. Pfizer breached the aforesaid implied warranties because Zoloft was not safe and effective for the treatment of women during pregnancy because it exposed the developing fetus to a significant risk of serious injury, and because the Mother Plaintiff's use of Zoloft for treatment during her pregnancy caused the Infant Plaintiff's injuries.

75. As a direct and proximate result of Pfizer's breach of implied warranties, Plaintiffs suffered injuries and damages, as set forth herein.

**WHEREFORE**, for the above reasons, Plaintiffs demand judgment in their favor and against Pfizer for an amount in excess of $50,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

## COUNT THREE – FRAUD

*(As Against Pfizer)*

76. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

77. Pfizer is liable to Plaintiffs under the state common law and/or state Product Liability Acts for fraudulently, intentionally, and/or negligently misrepresenting to the public, and to Plaintiffs, both directly and by and through the Mother Plaintiff's prescribing physicians, the safety and effectiveness of Zoloft when used by women of childbearing potential, and/or fraudulently, intentionally, and/or negligently concealing, suppressing or omitting material, adverse information regarding the safety and effectiveness of Zoloft when used by women of childbearing potential.

78. Pfizer's fraudulent, intentional, and/or negligent material misrepresentations and omissions regarding the safety and efficacy of Zoloft and of Zoloft's side effects, including the risk of congenital birth defects, were communicated to Plaintiffs directly through promotional materials, advertising, product inserts, and the monograph provided with Plaintiff's prescription with the intent that the Mother Plaintiff use Zoloft. The safety and efficacy of Zoloft was also fraudulently, intentionally, and/or negligently misrepresented to the Mother Plaintiff's prescribing physician with the intent that such misrepresentations would cause Zoloft to be prescribed to the Mother Plaintiff.

79. Pfizer either knew or should have known that the material representations they were making regarding Zoloft's safety, efficacy, and side effects were false.

80. Pfizer fraudulently, intentionally, and/or negligently made the misrepresentations and/or actively concealed, suppressed, or omitted this material information with the intention and specific desire to induce the Mother Plaintiff, the Mother Plaintiff's physician, and the consuming public to use and prescribe Zoloft.

81. Pfizer fraudulently, intentionally, and/or negligently knew or should have known that the Mother Plaintiff, the Mother Plaintiff's physician, and the consuming public would rely on such material misrepresentations and/or omissions in selecting Zoloft for the treatment of the Mother Plaintiff. Pfizer knew or should have known that the Mother Plaintiff and the Mother Plaintiff's physician would rely upon their false representations and/or omissions.

82. Pfizer fraudulently, intentionally, and/or negligently made the misrepresentations and/or actively concealed, suppressed, or omitted this material information with the intention and specific desire to induce the Mother Plaintiff, the Mother Plaintiff's physician, and the consuming public to use and prescribe Zoloft. Pfizer fraudulently, intentionally, and/or negligently knew or should have known that the Mother Plaintiff, the Mother Plaintiff's physician, and the consuming public would rely on such material misrepresentations and/or omissions in selecting Zoloft for the treatment of the Mother Plaintiff. Pfizer knew or should have known that the Mother Plaintiff and the Mother Plaintiff's physician would rely upon their false representations and/or omissions.

83. Pfizer made these material misrepresentations and/or omissions and actively concealed adverse information at a time when they, their agents and/or their employees knew or should have known that Zoloft had defects, dangers, and characteristics that were other than what had been represented to the medical community and the consuming public, including the Plaintiffs herein. Those misrepresentations and omissions further include, but are not limited to, the following particulars:

a) Pfizer failed to disclose or concealed that their pre-clinical and clinical testing, and post-marketing surveillance was inadequate to determine the safety and side effects of Zoloft;

b) Pfizer failed to disclose or concealed data showing that Zoloft increased the risk of congenital birth defects;

c) Pfizer failed to include adequate warnings with Zoloft about the potential and actual risks, and nature, scope, severity, and duration of any serious side effects of this drug, including, without limitation, the increased risk of congenital birth defects, other injuries and death, either compared to the use of alternative drug products in its class or compared to the use of no drug products; and/or

d) Pfizer concealed and continues to conceal past and present facts, including that as early as the 1990's, Pfizer was aware of and concealed their knowledge of an association between the use of Zoloft and dangerous side effects, including the increased risk of congenital birth defects, from the consuming public, including Plaintiffs and the Mother Plaintiff's physicians.

84. Pfizer's material misrepresentations and/or active concealment, suppression, and omissions were perpetuated directly and/or indirectly by Pfizer, their sales representatives, employees, distributors, agents, and/or detail persons, through the databases, printouts, monographs, and other information drafted, prepared, marketed, sold, and supplied by Pfizer, their sales representatives, employees, distributors, agents, and/or detail persons.

85. Pfizer's material misrepresentations and/or active concealment, suppression, and omissions constitute a continuing tort.

86. Through its product inserts, Pfizer continued to misrepresent the potential risks and complications associated with Zoloft.

87. Pfizer had a post-sale duty to warn physicians and Plaintiffs about the potential risks and complications associated with Zoloft they manufactured and sold in a timely manner.

88. Pfizer fraudulently, intentionally, and/or negligently misrepresented the safety and efficacy of Zoloft in their labeling, advertising, product inserts, promotional materials, or other marketing.

89. If Plaintiffs and the Mother Plaintiff's physicians had known the true facts concerning the risks of Zoloft, in particular, the risk of congenital birth defects, they would not have prescribed and used Zoloft, and would have instead prescribed and used one of the safer alternatives, or no drug.

90. Plaintiffs' and Plaintiff's physicians' reliance upon the Pfizer's material misrepresentations was justified, among other reasons, because said misrepresentations and omissions were made by individuals and entities who were in a position to know the true facts concerning Zoloft, while Plaintiffs and Plaintiff's physicians were not in a position to know the true facts, and because Pfizer overstated the benefits and safety of Zoloft, and concomitantly downplayed the risks of its use, including congenital birth defects, thereby inducing the Mother Plaintiff and the Mother Plaintiff's physician to use Zoloft, in lieu of other, safer alternatives, or no drug at all.

91. As a direct and proximate result of the Plaintiffs' and the Mother Plaintiff's physicians' reliance on Pfizer's misrepresentations and concealment concerning the risks and benefits of Zoloft, Plaintiffs suffered injuries and damages, as set forth herein.

**WHEREFORE**, for the above reasons, Plaintiffs demand judgment in their favor and against Pfizer for an amount in excess of $50,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

**COUNT FOUR – INTENTION INFLICTION OF EMOTIONAL DISTRESS**

92. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

93. Pfizer is liable to Plaintiffs under state common law and/or the applicable state Product Liability Acts for its intentional infliction of emotional distress, which has, and will continued to be suffered by Plaintiffs.

94. Pfizer by and through its conduct described herein intentionally inflicted emotional distress upon Plaintiffs. Pfizer by and through its conduct described herein act in a manner, which was extreme, outrageous. Pfizer acted with flagrant and malicious disregard of Plaintiffs' health and safety.

95. Pfizer was subjectively aware of the extreme risks posed by its acts and/or omissions but did nothing to rectify them. Pfizer's conduct described herein involved an extreme degree of risk considering the probability and magnitude of potential harm to Plaintiffs and others. Pfizer had actual, subjective awareness of the risks, and consciously disregarded such risks.

96. Pfizer knowingly withheld, concealed or misrepresented the risks and dangers of Zoloft and the Zoloft information and warnings, including the risk of congenital birth defects, from both the medical community and the public at large, including Plaintiffs, their physicians and pharmacists.

97. Pfizer downplayed, understated, and disregarded their knowledge of the serious and permanent side effects associated with the use of Zoloft, including congenital birth defects, despite information demonstrating Zoloft was unreasonably dangerous and in conscious disregard of the risk of serious injury posed to Plaintiffs by these known misrepresentations and/or omissions.

98. Pfizer misled both the medical community and the public at large, including Plaintiffs, their physicians and pharmacists, by making false representations about and concealing pertinent information regarding Zoloft and its information and warnings.

99. Pfizer downplayed, understated and disregarded its knowledge of the serious and permanent side effects associated with the use of Zoloft, including congenital birth defects, despite information demonstrating the product was unreasonably dangerous.

100. Pfizer knew that Zoloft had unreasonably dangerous risks and caused serious side effects of which Plaintiffs, their physicians and pharmacists would not be aware. Pfizer nevertheless advertised, analyzed, assembled, compounded, designed, developed, distributed, formulated, inspected, labeled, manufactured, marketed, packaged, produced, promoted, processed, researched, sold, and tested Zoloft knowing that there were safer methods and products available.

101. Pfizer's actions were performed willfully, deliberately, intentionally, and with reckless disregard for the rights and safety of Plaintiffs and the public and caused substantial financial injury.

102. The conduct of Pfizer, undertaken with knowledge, for these purposes, evidences gross negligence and a willful, wanton, and conscious disregard for the rights and safety of consumers, including the Plaintiffs, and as a direct and proximate result of the Pfizer's actions and inactions, Plaintiffs suffered injuries due to Pfizer's disregard for Plaintiffs' rights and safety.

103. As a direct and proximate result of the actions and/or omissions of the Pfizer, Plaintiffs have and will continue to suffer, the past and future injuries, damages, and losses as a result of the Infant Plaintiff's injuries, as set forth herein.

104. Pfizer is liable to Plaintiffs for all general, special, and punitive damages, delay damages, and other relief to which they are entitled by law.

**WHEREFORE**, for the above reasons, Plaintiffs demand judgment in their favor and against Pfizer for an amount in excess of $50,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

## COUNT FIVE - LOSS OF CONSORTIUM AND PECUNIARY LOSS

*(As Against Pfizer)*

105. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

106. Pfizer is liable to Plaintiffs under state common law and/or the applicable state product liability acts.

107. As a direct and proximate result of the actions and inactions of Pfizer as set forth above, Plaintiffs were exposed to Zoloft and the Parent Plaintiffs have suffered, and will continue to suffer, the past and future injuries, damages, and losses as a result of the Infant Plaintiff's injuries, as set forth herein.

108. Pfizer is liable to Parent Plaintiffs for all general, special, and punitive damages, delay damages, and other relief to which they are entitled by law.

**WHEREFORE**, for the above reasons, Plaintiffs demand judgment in their favor and against Pfizer for an amount in excess of $50,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

**COUNT SIX & SEVEN – NEGLIGENCE & NEGLIGENCE PER SE**
*(As Against Pfizer)*

***A. NEGLIGENCE & NEGLIGENCE PER SE***

109. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

110. Pfizer is liable to Plaintiffs pursuant to state common law and/or state Product Liability Acts due to their negligent advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packing, producing, promoting, processing, researching, selling and testing Zoloft.

111. At all times mentioned herein, Pfizer was under a duty to exercise reasonable care in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packing, producing, promoting, processing, researching, selling, and testing Zoloft to ensure that use of Zoloft did not result in avoidable injuries.

112. At all times relevant to this lawsuit, Pfizer owed a duty to consumers, including Plaintiffs and their health care providers, to assess, manage, and communicate the risks, dangers, and adverse effects of Zoloft, and to warn the medical community, consumers, the Plaintiffs, and the Mother Plaintiff's physicians of those risks, dangers, and adverse effects.

113. Pfizer's duties included, but were not limited to, carefully and properly advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packing, producing, promoting, processing, researching, selling, and testing Zoloft, which was placed in the stream of commerce, and providing adequate information regarding the appropriate use of Zoloft.

114. Pfizer negligently and carelessly breached the above-described duties to Plaintiffs by committing negligent acts and/or omissions, including, but not limited to, the following:

a) Failing to ensure Zoloft's warnings to the medical community, physicians, the Mother Plaintiff's physicians, and Plaintiffs were accurate and adequate, despite having extensive knowledge of the risks associated with Zoloft;

b) Failing in their obligation to provide the medical community, physicians, the Mother Plaintiff's physicians, and Plaintiffs with adequate and clinically relevant information, and data and warnings regarding the adverse health risks associated with exposure to Zoloft, and/or that there existed safer and more or equally effective alternative drug products;

c) Failing to conduct post market safety surveillance and report that information to the medical community, physicians, the Mother Plaintiff's physicians, and Plaintiffs;

d) Failing to include adequate warnings and/or provide adequate and clinically relevant information and data that would alert the

medical community, physicians, the Mother Plaintiff's physicians, and Plaintiffs to the dangerous risks of Zoloft;

e) Failing to continually monitor, test, and analyze data regarding safety, efficacy, and the prescribing practices for Zoloft;

f) Failing to review all adverse drug event information (AER) and to report any information bearing upon the adequacy and/or accuracy of their warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Zoloft to the medical community, physicians, the Mother Plaintiff's physicians, and Plaintiffs;

g) Failing to provide adequate post-marketing warnings and instructions after Pfizer knew or should have known of the significant risks of, among other things, congenital birth defects of Zoloft;

h) Failing to periodically review all medical literature regarding Zoloft and failing to report data, regardless of the degree of significance, regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Zoloft;

i) Failing to disclose the results of the testing and other information in their possession regarding the possibility that Zoloft can interfere with the proper development of an unborn fetus;

j) Failing to warn adequately the medical community, physicians, the Mother Plaintiff's physicians, and Plaintiffs of the dangers of using Zoloft during pregnancy, including the risk of congenital birth defects;

k) Representing that Zoloft was safe for use during pregnancy when, in fact, Pfizer knew or should have known that Zoloft was unsafe for this use and that Zoloft was associated with congenital birth defects;

l) Promoting and marketing Zoloft for use with pregnant women, despite the fact that the Pfizer knew or should have known that Zoloft was associated with an increased risk of congenital abnormalities;

m) Promoting and marketing Zoloft as safe and effective for use with pregnant women when, in fact, it was unsafe;

n) Promoting and marketing Zoloft for non-approved (off-label) uses and/or illegally over-promoting, marketing, advertising, and selling Zoloft in a zealous and unreasonable way, without regard to the potential danger that it posed for an unborn fetus;

o) Failing to independently monitor their sales of Zoloft and the medical literature, which would have alerted them to the fact that Zoloft was widely over-prescribed to women of childbearing potential as a result of inadequate warnings in the package inserts and PDR monographs for Zoloft, and as a result of the over-promotion of Zoloft;

p) Failing to act as a reasonably prudent drug manufacturer in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packing, producing, promoting, processing, researching, selling, and testing Zoloft;

q) Failing to perform adequate and necessary studies to determine and analyze the safety and risks associated with Zoloft's use;

r) Failing to use ordinary care in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packing, producing, promoting, processing, researching, selling, and testing Zoloft so as to reveal and communicate the risk of congenital birth defects to the medical community, the Mother Plaintiff's physicians, and Plaintiffs;

s) Failing to accompany Zoloft with adequate information that would alert the medical community, the Mother Plaintiff's physicians, and Plaintiffs to the potential adverse side effects associated with the use of Zoloft and the nature, severity, and duration of such adverse effects;

t) Failing to conduct adequate post-marketing studies, non-clinical and clinical testing, and post-marketing surveillance and analyses to determine and communicate the safety profile and side effects of Zoloft;

u) Continuing to promote the safety and effectiveness of Zoloft, while downplaying their risks, even after Pfizer knew or should have known of the risks of Zoloft;

v) Failing to provide consumers, such as Plaintiffs and Plaintiffs' physicians, with scientific data which indicated that Zoloft was unreasonably dangerous, and that there were no women of childbearing potential and/or pregnant women in whom the benefits of Zoloft outweighed the risks;

w) Being careless and negligent in that Pfizer knew or should have known that Zoloft was a substance that would be actively transported through the placenta during pregnancy and could inhibit the health and development of the fetus;

x) Negligently and carelessly promoting Zoloft as safe and effective for use with women of childbearing potential and/or pregnant women when, in fact, it was unsafe;

y) Negligently and carelessly over-promoting Zoloft in a zealous and unreasonable way, without regard to the potential danger that it posed to an unborn fetus; and/or

z) Negligently and carelessly failing to act as a reasonably prudent drug manufacturer, distributor, marketer, promoter, or seller would under same or similar circumstances.

115. Although Pfizer knew or should have known that Zoloft caused unreasonably dangerous side effects, including congenital birth defects, Pfizer continued to market Zoloft, despite the fact there were safer and more or equally effective alternative drug products.

116. Pfizer knew or should have known that consumers, such as Plaintiffs, would suffer injury as a result of Pfizer's failure to exercise ordinary care, as described above.

117. The conduct of Pfizer was a direct and proximate cause of Plaintiffs' injuries. Pfizer knew or should have known that Zoloft could be dangerous and unsafe for pregnant women and the developing fetus.

118. The conduct described herein violated applicable state statutes constituting negligence *per se*.

119. As a direct and proximate result of the negligent acts and/or omissions of Pfizer as set forth above, Plaintiffs suffered, and will continue to suffer into the future, injuries and damages, as set forth herein.

***B. NEGLIGENT DESIGN***

120. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

121. Pfizer is liable to Plaintiffs under state common law and/or the applicable state Product Liability Acts for the negligent design of Zoloft.

122. At all times relevant to this lawsuit, Pfizer owed a duty to consumers, including Plaintiffs and their health care providers, to exercise reasonable care in the design of Zoloft.

123. Pfizer negligently and carelessly breached this duty of care to Plaintiffs because they designed Zoloft which:

a) Was and is unreasonably defective in design because it is a teratogenic compound that unreasonably increased the risks of congenital birth defects;

b) Was and is defective in design and was not reasonably safe as intended to be used, subjecting Plaintiffs to risks which exceeded the benefits of Zoloft;

c) Was and is defective in design, making use of Zoloft more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with the Mother Plaintiff's underlying condition;

d) Was and is defective in design, making use of Zoloft more dangerous than the ordinary consumer would expect and more dangerous than other risks associated with like products;

e) Was and is defective in design in that it contained insufficient, incorrect and defective warnings in that they failed to alert physicians and users, including the Mother Plaintiff of the risks of adverse effects;

f) Was and is defective in design in that it was not safe for its intended use and was inadequately tested;

g) Was and is defective in design because its risks exceeded any benefit of Zoloft; and/or

h) Failed to act as a reasonably prudent drug manufacturer, seller, promoter, distributor, or marketer would have acted with respect to the design of Zoloft.

124. The conduct described herein violated applicable state statutes constituting negligence *per se*.

125. As a direct and proximate result of the negligent acts and/or omissions of the Pfizer, Plaintiffs suffered injuries and damages, as set forth herein.

***C. CONSTRUCTIVE FRAUD***

126. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

127. Pfizer is liable to Plaintiffs under state common law and/or the applicable state Product Liability Acts for constructive fraud in the manufacturing, distribution, and sale of Zoloft.

128. At the time Zoloft was manufactured, distributed, and sold by Pfizer to Plaintiffs, Pfizer was in a unique position of knowledge concerning the safety and effectiveness of Zoloft, which Plaintiffs or the Mother Plaintiff's physicians did not possess knowledge, and Pfizer thereby held a position of superiority over Plaintiffs.

129. Through their unique knowledge and expertise regarding the defective nature of Zoloft, and through their marketing statements to physicians and patients in advertisements, promotional materials, and other communications, Pfizer professed that they were in possession of facts demonstrating that Zoloft was safe and effective for its intended use and was not defective.

130. Pfizer's representations to the Mother Plaintiff's physicians were made to induce the purchase of Zoloft, and Plaintiffs and their physicians relied upon those statements when purchasing and administering Zoloft.

131. Pfizer took unconscionable advantage of their dominant position of knowledge with regard to Plaintiffs and their physicians and engaged in constructive fraud in their relationship.

132. Plaintiffs and the Mother Plaintiff's physicians reasonably relied on Pfizer's representations.

133. The conduct described herein violated applicable state statutes constituting negligence *per se*.

134. As a direct and proximate result of Pfizer's constructive fraud, Plaintiffs have suffered injuries and damages, as set forth herein.

**WHEREFORE**, for the above reasons, Plaintiffs demand judgment in their favor and against Pfizer for an amount in excess of $50,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

**COUNT EIGHT – NEGLIGENT PHARMACOVIGILANCE**
*(As Against Pfizer)*

135. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

136. Pfizer has an ongoing duty of pharmacovigilance. As part of this duty, Pfizer is required to continually monitor, test and analyze data regarding the safety, efficacy and prescribing practices of its marketed drugs, including Zoloft. Pfizer continually receives reports from its own clinical trials, practicing physicians, individual patients and regulatory authorities of adverse events that occur in patients taking Zoloft and its other marketed drugs. Furthermore, Pfizer continues to conduct clinical trials for its marketed drugs long after the drug is approved for use.

137. Pfizer has a duty to inform doctors, regulatory agencies and the public of new safety and efficacy information it learns, or should have learned, about its marketed drugs once that information becomes available to Pfizer, whether through Pfizer clinical trials, other outside sources or pharmacovigilance activities.

138. Specifically, when Pfizer learns, or should have learned, of new safety information associated with its marketed drugs, it has a duty to promptly disseminate that data to the public. Pfizer also has a duty to monitor epidemiological and pharmacovigilance data regarding its marketed drugs and promptly report any safety concerns that arise through epidemiologic study or data.

139. Pfizer breached its duty with respect to Plaintiffs. Pfizer, through various sources, including but not limited to, clinical trials and other adverse event reports, learned that there was a substantial risk of congenital birth defects, heart defects, omphalocele, PPHN and other related conditions, associated with Zoloft use during pregnancy and failed to inform doctors, regulatory agencies and the public of this risk. Pfizer had the means and the resources to perform its pharmacovigilance duties for the entire time Zoloft has been on the market in the United States.

140. The Infant Plaintiff suffer from physical injuries, the full extent of which have not yet been determined, some or all of which are permanent and/or fatal, and the Infant Plaintiff may suffer in the future from other diseases or conditions which have not yet been diagnosed.

141. As a direct and proximate result of the aforesaid conduct of Pfizer, the Plaintiffs have sustained pecuniary loss resulting from the pain and suffering caused by Infant Plaintiff's congenital birth defects, omphalocele PPHN and/or other related conditions, by the surgeries and procedures he has already undergone, and the surgeries and procedures that he will need to undergo in the future, as well as his inability to enjoy his life as a normal child without the presence of congenital birth defects, omphalocele, PPHN and/or other related conditions and additional general and special damages in a sum in excess of the jurisdictional minimum of this Court.

142. As a direct and proximate result of the aforesaid conduct of Pfizer, Parent Plaintiffs have incurred loss of consortium, general, special and medical damages and related expenses in an amount in excess of the jurisdictional minimum of this Court.

143. As a direct and proximate result of the aforesaid conduct of Pfizer, Parent Plaintiffs have sustained pecuniary loss resulting from the loss of their child's society, companionship, comfort, attention, protection, care, love, affection, advice, services, moral support, economic support and general and special damages in a sum in excess of the jurisdictional minimum of this Court.

144. The conduct of Pfizer, as described herein, was intentional, malicious, wanton, willful or oppressive or was done with gross negligence and reckless indifference to the Plaintiffs, and the public's safety and welfare.

**WHEREFORE**, for the above reasons, Plaintiffs demand judgment in their favor and against Pfizer for an amount in excess of $50,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

## COUNT NINE – STRICT PRODUCT LIABILITY – FAILURE TO WARN

*(As Against Pfizer)*

145. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

146. Pfizer is liable to Plaintiffs under state common law and/or the applicable state Product Liability Acts for the negligent and/or willful failure to provide adequate warnings and other clinically relevant information and data regarding the appropriate use of Zoloft to the Plaintiffs and the Mother Plaintiff's prescribing physicians.

147. Pfizer, as a manufacturer of pharmaceutical drugs, is held to the level of knowledge of an expert in the field, and further, Pfizer knew or should have known that the warnings and other clinically relevant information and data which they distributed regarding the risks of congenital birth defects associated with the use of Zoloft were inadequate.

148. Plaintiffs, and the Mother Plaintiff's prescribing physicians, did not have the same knowledge as Pfizer and no adequate warning or other clinically relevant information and data was communicated to them or to their physicians.

149. Pfizer had a continuing duty to provide consumers, including Plaintiffs and their physicians, with warnings and other clinically relevant information and data regarding the risks and dangers associated with Zoloft as it became or could have become available to Pfizer.

150. Pfizer manufactured, marketed, promoted, distributed, and sold an unreasonably dangerous and defective prescription drug, Zoloft in the stream of commerce, to health care providers empowered to prescribe and dispense Zoloft to consumers, including Mother Plaintiff, without adequate warnings and other clinically relevant information and data. Through both omissions and affirmative misstatements, Pfizer misled the medical community about the risks and benefits of Zoloft, which resulted in injury to Plaintiffs.

151. Despite the fact that Pfizer knew or should have known that Zoloft caused unreasonable and dangerous side effects, including congenital birth defects, they continued to manufacture, market, promote, distribute, and sell Zoloft without stating that there existed safer and more or equally effective alternative drug products and/or providing adequate clinically relevant information and data.

152. Pfizer knew or should have known that consumers and Plaintiffs specifically, would foreseeably and needlessly suffer injury as a result of the Pfizer's failures.

153. Pfizer breached their duty to provide timely and adequate warnings, instructions, and information, in the following particulars:

a) Failing to ensure Zoloft warnings to the medical community,

physicians, the Mother Plaintiff's physicians, and Plaintiffs were accurate and adequate despite having extensive knowledge of the risks associated with Zoloft;

b) Failing in their obligation to provide the medical community, physicians, the Mother Plaintiff's physicians, and Plaintiffs with adequate clinically relevant information, and data and warnings regarding the adverse health risks associated with exposure to Zoloft, and/or that there existed safer and more or equally effective alternative drug products;

c) Failing to conduct post market safety surveillance and report that information to the medical community, the Mother Plaintiff's physicians, and Plaintiffs;

d) Failing to include adequate warnings and/or providing adequate and clinically relevant information and data that would alert the medical community, the Mother Plaintiff's physicians, and Plaintiffs to the dangerous risks of Zoloft, including, among other things, the association with congenital birth defects;

e) Failing to continually monitor, test, and analyze data regarding safety, efficacy, and prescribing practices of their marketed drugs, including Zoloft;

f) Failing to review all adverse drug event information (AER) and to report any information bearing upon the adequacy and/or accuracy of their warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Zoloft to the medical community, the Mother Plaintiff's physicians, and Plaintiffs;

g) Failing to provide adequate post-marketing warnings and instructions after Pfizer knew or should have known of the significant risks of, among other things, congenital birth defects of Zoloft;

h) Failing to periodically review all medical literature regarding Zoloft and failing to report data, regardless of the degree of significance, regarding the adequacy and/or accuracy of their warnings, efficacy, or safety of Zoloft;

i) Failing to disclose the results of the testing and other information in their possession regarding the possibility that Zoloft can interfere with the proper development of an unborn

fetus;

j) Failing to warn adequately the medical community, the general public, and Plaintiffs of the dangers of using Zoloft during pregnancy, including the risk of congenital birth defects; and/or

k) Representing that Zoloft was safe for use during pregnancy, when in fact Pfizer knew or should have known that Zoloft was unsafe for this use and that Zoloft was associated with congenital birth defects.

154. Pfizer continued to aggressively manufacture, market, promote, distribute, and sell Zoloft, even after they knew or should have known of the unreasonable risks of congenital birth defects from Zoloft.

155. Pfizer had an obligation to provide Plaintiffs and the Mother Plaintiff's physicians with adequate and clinically relevant information, and data and warnings regarding the adverse health risks associated with exposure to Zoloft, and/or that there existed safer and more or equally effective alternative drug products.

156. By failing to provide Plaintiffs and the Mother Plaintiff's physicians with adequate, clinically relevant information, and data and warnings regarding the adverse health risks associated with exposure to Zoloft, and/or to inform them that there existed safer and more or equally effective alternative drug products, Pfizer breached their duty of reasonable care and safety.

157. As a direct and proximate result of the actions and inactions of Pfizer as set forth above, Plaintiffs were exposed to Zoloft, as a result suffered, and continue to suffer, the injuries and damages, as set forth herein.

**WHEREFORE**, for the above reasons, Plaintiffs demand judgment in their favor and against Pfizer for an amount in excess of $50,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

**COUNT TEN – MISREPRESENTATION AND SUPPRESSION**
*(As Against Pfizer)*

158. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

159. Pfizer is liable to Plaintiffs under the state common law and/or state Product Liability Acts for negligently misrepresenting to the public, and to Plaintiffs, both directly and by and through the Mother Plaintiff's prescribing physicians, the safety and effectiveness of Zoloft when used by women of childbearing potential, and/or negligently concealing, suppressing or omitting material, adverse information regarding the safety and effectiveness of Zoloft when used by women of childbearing potential.

160. Pfizer's negligent material misrepresentations and omissions regarding the safety and efficacy of Zoloft and of Zoloft's side effects, including the risk of congenital birth defects, were communicated to Plaintiffs directly through promotional materials, advertising, product inserts, and the monograph provided with Plaintiff's prescription with the intent that the Mother Plaintiff use Zoloft. The safety and efficacy of Zoloft was also negligently misrepresented to the Mother Plaintiff's prescribing physician with the intent that such misrepresentations would cause Zoloft to be prescribed to the Mother Plaintiff.

161. Pfizer either knew or should have known that the material representations they were making regarding Zoloft's safety, efficacy, and side effects were false.

162. Pfizer negligently made the misrepresentations and/or actively concealed, suppressed, or omitted this material information with the intention and specific desire to induce the Mother Plaintiff, the Mother Plaintiff's physician, and the consuming public to use and prescribe Zoloft. Pfizer knew or should have known that the Mother Plaintiff, the Mother Plaintiff's physician, and the consuming public would rely on such material misrepresentations and/or omissions in selecting Zoloft for the treatment of the Mother Plaintiff. Pfizer knew or should have known that the Mother Plaintiff and the Mother Plaintiff's physician would rely upon their false representations and/or omissions.

163. Pfizer negligently made the misrepresentations and/or actively concealed, suppressed, or omitted this material information with the intention and specific desire to induce the Mother Plaintiff, the Mother Plaintiff's physician, and the consuming public to use and prescribe Zoloft.

164. Pfizer negligently knew or should have known that the Mother Plaintiff, the Mother Plaintiff's physician, and the consuming public would rely on such material misrepresentations and/or omissions in selecting Zoloft for the treatment of the Mother Plaintiff. Pfizer knew or should have known that the Mother Plaintiff and the Mother Plaintiff's physician would rely upon their false representations and/or omissions.

165. Pfizer made these material misrepresentations and/or omissions and actively concealed adverse information at a time when they, their agents and/or their employees knew or should have known that Zoloft had defects, dangers, and characteristics that were other than what had been represented to the medical community and the consuming public, including the Plaintiffs herein. Those misrepresentations and omissions further include, but are not limited to, the following particulars:

a) Pfizer failed to disclose or concealed that their pre-clinical and clinical testing, and post-marketing surveillance was inadequate to determine the safety and side effects of Zoloft;

b) Pfizer failed to disclose or concealed data showing that Zoloft increased the risk of congenital birth defects;

c) Pfizer failed to include adequate warnings with Zoloft about the potential and actual risks, and nature, scope, severity, and duration of any serious side effects of this drug, including, without limitation, the increased risk of congenital birth defects, other injuries and death, either compared to the use of alternative drug products in its class or compared to the use of no drug products; and/or

d) Pfizer concealed and continues to conceal past and present facts, including that as early as the 1990's, Pfizer was aware of and concealed their knowledge of an association between the use of Zoloft and dangerous side effects, including the increased risk of congenital birth defects, from the consuming public, including Plaintiffs and the Mother Plaintiff's physicians.

166. Pfizer's material misrepresentations and/or active concealment, suppression, and omissions were perpetuated directly and/or indirectly by Pfizer, their sales representatives, employees, distributors, agents, and/or detail persons, through the databases, printouts, monographs, and other information drafted, prepared, marketed, sold, and supplied by Pfizer, their sales representatives, employees, distributors, agents, and/or detail persons.

167. Pfizer's material misrepresentations and/or active concealment, suppression, and omissions constitute a continuing tort.

168. Through its product inserts, Pfizer continued to misrepresent the potential risks and complications associated with Zoloft.

169. Pfizer had a post-sale duty to warn physicians and Plaintiffs about the potential risks and complications associated with Zoloft they manufactured and sold in a timely manner.

170. Pfizer negligently misrepresented the safety and efficacy of Zoloft in their labeling, advertising, product inserts, promotional materials, or other marketing.

171. If Plaintiffs and the Mother Plaintiff's physicians had known the true facts concerning the risks of Zoloft, in particular, the risk of congenital birth defects, they would not have prescribed and used Zoloft, and would have instead prescribed and used one of the safer alternatives, or no drug.

172. Plaintiffs' and Plaintiff's physicians' reliance upon the Pfizer's material misrepresentations was justified, among other reasons, because said misrepresentations and omissions were made by individuals and entities who were in a position to know the true facts concerning Zoloft, while Plaintiffs and Plaintiff's physicians were not in a position to know the true facts, and because Pfizer overstated the benefits and safety of Zoloft, and concomitantly downplayed the risks of its use, including congenital birth defects, thereby inducing the Mother Plaintiff and the Mother Plaintiff's physician to use Zoloft, in lieu of other, safer alternatives, or no drug at all.

173. As a direct and proximate result of the Plaintiffs' and the Mother Plaintiff's physicians' reliance on Pfizer's misrepresentations and concealment concerning the risks and benefits of Zoloft, Plaintiffs suffered injuries and damages, as set forth herein.

**WHEREFORE**, for the above reasons, Plaintiffs demand judgment in their favor and against Pfizer for an amount in excess of $50,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

**COUNT ELEVEN – PUNITIVE DAMAGES**
*(As Against Pfizer)*

174. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

175. Plaintiffs are entitled to punitive damages, pursuant to state common law or the applicable statutory provision, because the Pfizer's actions were reckless and without regard for the public's safety and welfare. Pfizer knowingly withheld, concealed or misrepresented the risks and dangers of Zoloft and the Zoloft information and warnings, including the risk of congenital birth defects, from both the medical community and the public at large, including Plaintiffs, their physicians and pharmacists.

176. Pfizer downplayed, understated, and disregarded their knowledge of the serious and permanent side effects associated with the use of Zoloft, including congenital birth defects, despite information demonstrating Zoloft was unreasonably dangerous and in conscious disregard of the risk of serious injury posed to Plaintiffs by these known misrepresentations and/or omissions.

177. Plaintiffs are entitled to punitive damages, pursuant to state common law or the applicable statutory provision, because Pfizer's actions were reckless and without regard for the public's safety and welfare. Pfizer misled both the medical community and the public at large, including Plaintiffs, their physicians and pharmacists, by making false representations about and concealing pertinent information regarding Zoloft and its information and warnings.

178. Pfizer downplayed, understated and disregarded its knowledge of the serious and permanent side effects associated with the use of Zoloft, including congenital birth defects, despite information demonstrating the product was unreasonably dangerous.

179. At all times material hereto, the Pfizer had a duty to exercise reasonable care in the advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packing, producing, promoting, processing, researching, selling, and/or testing Zoloft.

180. The conduct of the Pfizer in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packing, producing, promoting, processing, researching, selling, and/or testing Zoloft, and in failing to warn Plaintiffs, the Mother's Plaintiff physicians, pharmacists and other members of the public of the dangers inherent in the use of Zoloft, which were known to Pfizer, was attended by circumstances of fraud, malice, or willful and wanton conduct, done heedlessly and recklessly, without regard to consequences, or of the rights and safety of others, including Plaintiffs.

181. Pfizer knew that Zoloft had unreasonably dangerous risks and caused serious side effects of which Plaintiffs, their physicians and pharmacists would not be aware. Pfizer nevertheless advertised, analyzed, assembled, compounded, designed, developed, distributed, formulated, inspected, labeled, manufactured, marketed, packaged, produced, promoted, processed, researched, sold, and tested Zoloft knowing that there were safer methods and products available.

182. Pfizer's actions were performed willfully, deliberately, intentionally, and with reckless disregard for the rights and safety of Plaintiffs and the public and caused substantial financial injury.

183. Pfizer's conduct, undertaken with knowledge, for these purposes, evidences gross negligence and a willful, wanton, and conscious disregard for the rights and safety of consumers, including the Plaintiffs, and as a direct and proximate result of the Pfizer's actions and inactions, Plaintiffs suffered injuries due to Pfizer's disregard for Plaintiffs' rights and safety, and therefore, Plaintiffs are entitled to an award of punitive damages from Pfizer.

**WHEREFORE**, for the above reasons, Plaintiffs demand judgment in their favor and against the Pfizer for an amount in excess of $50,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

## COUNT TWELVE – STRICT PRODUCTS LIABILITY

*(As Against Pfizer)*

184. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

185. Pfizer is liable to Plaintiffs under state common law and/or the applicable state Product Liability Acts.

186. Pfizer manufactured, marketed, promoted, distributed, and sold Zoloft in the stream of commerce which was:

a. Unreasonably defective in design because it is a teratogenic compound that unreasonably increased the risks of congenital birth defects;

b. Defective in design and was not reasonably safe as intended to be used, subjecting Plaintiffs to risks which exceeded the benefits of Zoloft;

c. Defective in design, making use of Zoloft more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with Plaintiff's underlying condition;

d. Defective in design, making use of Zoloft more dangerous than the ordinary consumer would expect and more dangerous than other risks associated with like products;

e. Defective in design in that Zoloft contained insufficient, incorrect, and defective warnings in that they failed to alert physicians and users, including Plaintiffs, of the risks of adverse effects; and/or

f. Defective in design in that Zoloft was not safe for its intended use and was inadequately tested.

187. Pfizer knew and intended that Zoloft would be used by consumers, including the Mother Plaintiff, without any inspection for defects, and that the Mother Plaintiff and her physicians would rely upon the representations made by Pfizer on Zoloft's product labels and otherwise.

188. Prior to the manufacturing, sale, and distribution of Zoloft, Pfizer knew, or was reckless in not knowing, that Zoloft was in a defective condition.

189. The Mother Plaintiff used Zoloft for its intended purpose and could not have discovered any defect therein through the exercise of due care.

190. At the time that Pfizer manufactured, marketed, promoted, distributed, and sold Zoloft there existed safer and more or equally effective alternative drug products.

191. As a direct and proximate result of the actions and inactions of Pfizer as set forth above, Plaintiffs were exposed to Zoloft, and as a result, suffered, and continue to suffer, injuries and damages, as set forth herein.

**WHEREFORE**, for the above reasons, Plaintiffs demand judgment in their favor and against Pfizer for an amount in excess of $50,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

**COUNT FOURTEEN – VIOLATION OF CONSUMER PROTECTION ACTS**
*(As Against Pfizer)*

192. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

193. Pfizer is liable to Plaintiffs under state common law and/or the applicable state consumer protection acts. Pfizer manufactured, marketed, promoted, distributed, and sold Zoloft in the stream of commerce which was:

a. Unreasonably defective in design because it is a teratogenic compound that unreasonably increased the risks of congenital birth defects;

b. Defective in design and was not reasonably safe as intended to be used, subjecting Plaintiffs to risks which exceeded the benefits of Zoloft;

c. Defective in design, making use of Zoloft more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with Plaintiff's underlying condition;

d. Defective in design, making use of Zoloft more dangerous than the ordinary consumer would expect and more dangerous than other risks associated with like products;

e. Defective in design in that Zoloft contained insufficient, incorrect, and defective warnings in that they failed to alert physicians and users, including Plaintiffs, of the risks of adverse effects; and/or

f. Defective in design in that Zoloft was not safe for its intended use and was inadequately tested.

194. Pfizer knew and intended that Zoloft would be used by consumers, including the Mother Plaintiff, without any inspection for defects, and that the Mother Plaintiff and her physicians would rely upon the representations made by Pfizer on Zoloft's product labels and otherwise.

195. Prior to the manufacturing, sale, and distribution of Zoloft, Pfizer knew, or was reckless in not knowing, that Zoloft was in a defective condition. The Mother Plaintiff used Zoloft for its intended purpose and could not have discovered any defect therein through the exercise of due care.

196. At the time that Pfizer manufactured, marketed, promoted, distributed, and sold Zoloft there existed safer and more or equally effective alternative drug products. As a direct and proximate result of the actions and inactions of Pfizer as set forth above, Plaintiffs were exposed to Zoloft, and as a result, suffered, and continue to suffer, injuries and damages, as set forth herein.

197. Pfizer is liable to Plaintiffs for all general, special, and punitive damages, delay damages, and other relief to which they are entitled by law.

**WHEREFORE**, for the above reasons, Plaintiffs demand judgment in their favor and against Pfizer for an amount in excess of $50,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

**COUNT SIXTEEN – LOSS OF INCOME**
*(As Against Pfizer)*

198. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

199. As a direct and proximate result of the conduct of Pfizer, the Plaintiffs have incurred loss of income in an amount in excess of the jurisdictional minimum of this Court.

**WHEREFORE**, for the above reasons, Plaintiffs demand judgment in their favor and against Pfizer for an amount in excess of $50,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

**COUNT SEVENTEEN – MEDICAL EXPENSES**
*(As Against Pfizer)*

200. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

201. As a direct and proximate result of the conduct of Pfizer, Plaintiffs have incurred medical damages and related expenses in an amount in excess of the jurisdictional minimum of this Court.

**WHEREFORE**, for the above reasons, Plaintiffs demand judgment in their favor and against Pfizer for an amount in excess of $50,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

**COUNT EIGHTEEN – DESIGN DEFECT**
*(As Against Pfizer)*

202. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

203. Pfizer is liable to Plaintiffs under state common law and/or the applicable state Product Liability Acts.

204. Pfizer manufactured, marketed, promoted, distributed, and sold Zoloft in the stream of commerce which was:

a. Unreasonably defective in design because it is a teratogenic compound that unreasonably increased the risks of congenital birth defects;

b. Defective in design and was not reasonably safe as intended to be used, subjecting Plaintiffs to risks which exceeded the benefits of Zoloft;

c. Defective in design, making use of Zoloft more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with Plaintiff's underlying condition;

d. Defective in design, making use of Zoloft more dangerous than the ordinary consumer would expect and more dangerous than other risks associated with like products;

e. Defective in design in that Zoloft contained insufficient, incorrect, and defective warnings in that they failed to alert physicians and users, including Plaintiffs, of the risks of adverse effects; and/or

f. Defective in design in that Zoloft was not safe for its intended use and was inadequately tested.

205. Pfizer knew and intended that Zoloft would be used by consumers, including the Mother Plaintiff, without any inspection for defects, and that the Mother Plaintiff and her physicians would rely upon the representations made by Pfizer on Zoloft's product labels and otherwise.

206. Prior to the manufacturing, sale, and distribution of Zoloft, Pfizer knew, or was reckless in not knowing, that Zoloft was in a defective condition.

207. The Mother Plaintiff used Zoloft for its intended purpose and could not have discovered any defect therein through the exercise of due care.

208. At the time that Pfizer manufactured, marketed, promoted, distributed, and sold Zoloft there existed safer and more or equally effective alternative drug products.

209. As a direct and proximate result of the actions and inactions of Pfizer as set forth above, Plaintiffs were exposed to Zoloft, and as a result, suffered, and continue to suffer, injuries and damages, as set forth herein.

**WHEREFORE**, for the above reasons, Plaintiffs demand judgment in their favor and against Pfizer for an amount in excess of $50,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

## JURY DEMAND

210. Plaintiffs demand that all issues of fact in this case be tried to a properly empanelled jury.

## CONCLUSION AND PRAYER

**WHEREFORE**, Plaintiffs request trial by jury and that the Court grants them the following relief against the Defendants, on all counts of this Complaint, including:

(A) Money Damages representing fair, just, and reasonable compensation for their respective common law and statutory claims in excess of $50,000.00;

(B) Lost Wages

(C) Punitive and/or Treble Damages pursuant to state law;

(D) Attorneys' fees pursuant to state law;

(E) Pre-judgment and post-judgment interests as authorized by law on the judgments which enter on Plaintiffs' behalf;

(F) Costs of suit and expenses;

(G) Delay Damages; and

(H) Such other relief as is deemed just and appropriate.

**DATED: May 3, 2012**

Respectfully submitted,

**ARNOLD & ITKIN LLP**

BY: /s/

Kurt B. Arnold, Esquire
Jason A. Itkin, Esquire
1401 McKinney Street, Ste 2550
Houston, Texas 77010
Telephone: 713-222-3800
Telecopier: 713-222-3850

Rosemary Pinto, Esquire
PA Bar #53114
Feldman & Pinto
1604 Locust Street, 2nd Floor
Philadelphia, PA 19103
Telephone: 215-546-2604
Telecopier: 215-546-9904
**ATTORNEYS FOR PLAINTIFF**

**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the above and foregoing instrument has been forwarded to counsel of record, by the undersigned, pursuant to Pennsylvania Rules of Civil Procedure on the 3rd day of May, 2012.

Joseph E. O'Neil, Esquire
Carolyn McCormack, Esquire
Mary Grace Maley, Esquire
Lavin, O'Neil, Ricci, Cedrone & DiSipio
190 North Independence Mall West
6th & Race Streets
Philadelphia, PA 19106
Counsel for Defendants

/s/ Rosemary Pinto
Rosemary Pinto

PHILADELPHIA COURT OF COMMON PLEAS

# PETITION/MOTION COVER SHEET

| FOR COURT USE ONLY | |
|---|---|
| ASSIGNED TO JUDGE: | ANSWER/RESPONSE DATE: |

*Do not send Judge courtesy copy of Petition/Motion/Answer/Response. Status may be obtained online at http://courts.phila.gov*

**CONTROL NUMBER:** 12050436

***(RESPONDING PARTIES MUST INCLUDE THIS NUMBER ON ALL FILINGS)***

September (Month) Term, 2007 (Year)

No. 03275

PORTER ETAL VS SMITHKLINEBEECHAM CORP

Name of Filing Party: SMITHKLINE BEECHAM CORP-DFT

**INDICATE NATURE OF DOCUMENT FILED:**

☐ Petition *(Attach Rule to Show Cause)* ☐ Motion

☒ Answer to Petition ☐ Response to Motion

**Has another petition/motion been decided in this case?** ☐ Yes ☐ No

**Is another petition/motion pending?** ☐ Yes ☐ No

*If the answer to either question is yes, you must identify the judge(s):*

| TYPE OF PETITION/MOTION *(see list on reverse side)* | PETITION/MOTION CODE *(see list on reverse side)* |
|---|---|
| ANSWER (MOTION/PETITION) FILED | MTANS |

ANSWER / RESPONSE FILED TO (Please insert the title of the corresponding petition/motion to which you are responding):
MTAMD - MOTION TO AMEND

**I. CASE PROGRAM**

OTHER PROGRAM

Court Type: MASS TORT

Case Type: MASS TORT - PAXIL-BIRTH DEFECT

**II. PARTIES** *(required for proof of service)*

(Name, address and ***telephone number*** of all counsel of record and unrepresented parties. Attach a stamped addressed envelope for each attorney of record and unrepresented party.)

MARK S KARPO
137 N. 9TH ST. , PHILADELPHIA PA 19107

JOSEPH E ONEIL
190 N. INDEPENDENCE MALL WEST 6TH & RACE STREETS SUITE 500 , PHILADELPHIA PA 19106

MARY GRACE MALEY
190 N. INDEPENDENCE MALL WEST 6TH & RACE STREETS SUITE 500 , PHILADELPHIA PA 19106

CAROLYN L. McCORMACK
190 N. INDEPENDENCE MALL WEST 6TH & RACE STREETS SUITE 500 , PHILADELPHIA PA 19106

KURT B. ARNOLD
1401 MCKINNEY STREET , HOUSTON TX 77010

**III. OTHER**

By filing this document and signing below, the moving party certifies that this motion, petition, answer or response along with all documents filed, will be served upon all counsel and unrepresented parties as required by rules of Court (see PA. R.C.P. 206.6, Note to 208.2(a), and 440). Furthermore, moving party verifies that the answers made herein are true and correct and understands that sanctions may be imposed for inaccurate or incomplete answers.

| *(Attorney Signature/Unrepresented Party)* | May 23, 2012 *(Date)* | JOSEPH E. ONEIL *(Print Name)* | *(Attorney I.D. No.)* |
|---|---|---|---|

**The Petition, Motion and Answer or Response, if any, will be forwarded to the Court after the Answer/Response Date.**
**No extension of the Answer/Response Date will be granted even if the parties so stipulate.**

30-1061B E-File# 1205040692

23-MAY-12 14:49:26

MICHAEL E. PIERCE
1401 MCKINNEY STREET , HOUSTON TX 77010
ALEXANDER G. DWYER
ARNOLD & ITKIN, LLP 1401 MCKINNEY STREET STE 2550 , HOUSTON TX 77010

**LAVIN, O'NEIL, RICCI, CEDRONE & DISIPIO**

ATTORNEYS AT LAW

SUITE 500

190 NORTH INDEPENDENCE MALL WEST

6TH & RACE STREETS

PHILADELPHIA, PA 19106

(215) 627-0303

FAX: (215) 627-2551

WWW.LAVIN-LAW.COM

NEW YORK OFFICE
420 LEXINGTON AVENUE
GRAYBAR BUILDING
SUITE 335
NEW YORK, NY 10170
(212) 319-6898

FAX: (212) 319-6932

NEW JERSEY OFFICE
1300 ROUTE 73
SUITE 307
MT. LAUREL, NJ 08054
(856) 778-5544

FAX: (856) 793-0237

WRITER'S DIRECT DIAL NUMBER
(215) 351-7901

WRITER'S E-MAIL ADDRESS
JONEIL@LAVIN-LAW.COM

**May 23, 2012**

**PAXIL PREGNANCY**

**CONTROL NO.: 12050436**

**Opposing Counsel:**
**Arnold & Itkin LLP**
**Feldman & Pinto, P.C.**

The Honorable Sandra Mazer Moss
The Honorable Arnold L. New
Court of Common Pleas
of Philadelphia County
Complex Litigation Center
City Hall – Room 622
Philadelphia, PA 19107

Attention: Donna Candelora, Esquire

***Re:*** ***Robert Porter and Katherine Porter, Individually and as Parents and Natural Guardians of Robert T. "Bo" Porter, a Minor v. SmithKline Beecham Corporation d/b/a GlaxoSmithKline, Philadelphia CCP, September Term 2007, No. 003275***
***Our File No.: 08014-0214901***

**DEFENDANT GLAXOSMITHKLINE LLC'S RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION FOR LEAVE TO FILE FIRST AMENDED CIVIL ACTION COMPLAINT – SHORT FORM**

| | |
|---|---|
| ROBERT PORTER and KATHERINE PORTER, Individually and as Parents and Natural Guardians of ROBERT T. 'Bo' PORTER, A Minor | : PHILADELPHIA COUNTY<br>: COURT OF COMMON PLEAS |
| v. | : SEPTEMBER TERM, 2007<br>: NO. 003275 |
| SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE | : PAXIL – PREGNANCY |

**ORDER**

AND NOW, this ____ day of _____, 2012, upon consideration of Plaintiffs' Motion for Leave to File First Amended Civil Action Complaint – Short Form, the Response of Defendant GlaxoSmithKline LLC, and any reply thereto, and having considered the arguments of counsel, it is hereby ORDERED that GlaxoSmithKline LLC is dismissed and that this case be deferred and removed from the *In re Paxil Pregnancy Litigation* case list.

BY THE COURT:

_____
J.

Dear Judge Moss and Judge New:

Defendant GlaxoSmithKline LLC ("GSK") submits this Response in Opposition to Plaintiffs' Motion for Leave to File First Amended Civil Action Complaint – Short Form. GSK should be dismissed and the case should be deferred and removed from the *In re Paxil Pregnancy Litigation* case list.

## I. ARGUMENT

As an initial matter, GSK opposes Plaintiffs' Motion because GSK should no longer be a party to this case. Plaintiffs' counsel, Arnold & Itkin LLP, represented to GSK that they would dismiss this case as to GSK because it is undisputed that Plaintiff Katherine Porter took generic paroxetine, not branded Paxil, during her pregnancy with minor Plaintiff Robert "Bo" Porter. (*See* Medical Record at 559483.029.MED00001-00004, attached as Exhibit 1 (pharmacy record showing only generic paroxetine, manufactured by Andrx, during the pregnancy – from August 2005 through March 2006).) Plaintiffs' counsel should abide by its representations and dismiss GSK. Should they later wish to proceed against another defendant, that is their choice, but they cannot keep GSK in this case and simultaneously claim that they are not litigating against GSK.

Moreover, this case does not even belong on the *In re Paxil Pregnancy Litigation* case list. The Court has previously stated at Case Management Conferences that cases involving generic paroxetine should be deferred and removed from the *In re Paxil Pregnancy Litigation* case list. This case is no exception. Barring proof that Plaintiff Katherine Porter took branded Paxil, this case should be deferred.

## II. CONCLUSION

For the reasons set forth above, the Court should dismiss this case as to GSK, defer the case, and remove the case from the *In re Paxil Pregnancy Litigation* case list.

**Respectfully Submitted,**

**LAVIN, O'NEIL, RICCI, CEDRONE & DISIPIO**

By: /s/
Joseph E. O'Neil, Esquire (ID No. 29053)
Mary Grace Maley, Esquire (ID No. 37610)
Carolyn L. McCormack, Esquire (ID No. 87800)
*Attorneys for Defendant GlaxoSmithKline LLC, formerly SmithKline Beecham Corporation, d/b/a GlaxoSmithKline*

cc: Kurt B. Arnold, Esquire
Jason A. Itkin, Esquire
Michael E. Pierce, Esquire
Rosemary Pinto, Esquire

**CERTIFICATE OF SERVICE**

I hereby certify that I will serve a true and correct copy of **DEFENDANT GLAXOSMITHKLINE LLC, FORMERLY SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE'S RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION FOR LEAVE TO FILE FIRST AMENDED CIVIL ACTION COMPLAINT – SHORT FORM** in accordance with Pa. R.C.P. 440 on all parties not served electronically. All other parties will be electronically served by the court in accordance with Pa. R.C.P. 205.4(g) and by U.S. mail and/or electronic mail.

Kurt B. Arnold, Esquire
Jason A. Itkin, Esquire
Michael E. Pierce, Esquire
Arnold & Itkin LLP
1401 McKinney Street
Suite 2550
Houston, TX 77010

Rosemary Pinto, Esquire
Feldman & Pinto, P.C.
1604 Locust Street, 2R
Philadelphia, PA 19103
***Counsel for Plaintiffs***

**LAVIN, O'NEIL, RICCI, CEDRONE & DISIPIO**

Date: May 23, 2012

BY: */s/ Joseph E. O'Neil*
Joseph E. O'Neil, Esquire
Counsel for Defendant
GlaxoSmithKline LLC, formerly
SmithKline Beecham Corporation
d/b/a GlaxoSmithKline

# Exhibit 1

(Exhibit 1, 559483.029.MED00001-00004, has been deemed confidential, with copies provided to the Court and to opposing counsel.)

IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
TRIAL DIVISION-CIVIL

| | | |
|---|---|---|
| ROBERT PORTER and KATHERINE PORTER, Individually and as Parents and Natural Guardians of ROBERT T. "BO" PORTER, a minor, Plaintiffs<br>v.<br>GLAXOSMITHKLINE, PLC, Defendant | : | September Term, 2007<br>No. 3275<br><br>Control No. 12050436 |



ORDER

AND NOW, this 4TH day of June, 2012, upon consideration of Plaintiffs' Motion for Leave to File First Amended Short Form Complaint, and Defendant's response thereto, it is hereby **ORDERED** and **DECREED** said motion is **GRANTED IN PART.**

Plaintiffs are given leave to file their Amended Short Form Complaint within twenty (20) days from entry of this order.

It is FURTHER ORDERED that as there are allegations Plaintiff Mother took Zoloft and Paxil during her pregnancy, Plaintiffs must produce definitive proof of use during pregnancy of Paxil, in addition to any testimony or affidavit of Plaintiff Mother, her family and/or friends. Said proof must be a doctor's record, prescription or pharmacy record. If said proof is not supplied within thirty (30) days of the date of this order, Defendant GSK may file a motion to dismiss the action against it.

The granting of this motion is without prejudice to Pfizer to file a motion to dismiss for untimely filing of said motion to amend.

Porter Etal Vs Smithkli-ORDER

07090327500028

BY THE COURT:

Sandra Mazer Moss, J.
Coordinating Judge
Complex Litigation Center

**Rosemary Pinto, Esq.**
PA Bar #53114
**FELDMAN & PINTO**
1604 Locust Street, 2nd Floor
Philadelphia, PA 19103
Tel: 215-546-2604
Fax: 215-546-9904

**ARNOLD & ITKIN LLP**
**Kurt B. Arnold**
**Jason A. Itkin**
**Alexander G. Dwyer**
Admitted *pro hac vice*
Texas State Bar No.: 24039117
1401 McKinney St., Suite 2550
Houston, Texas 77010
Tel: 713-222-3800
Fax: 713-222-3850
***Attorneys for Plaintiff***



**This is Not An Arbitration Case. An Assessment of Damages Is Required.**

| | |
|---|---|
| **ROBERT PORTER and KATHERINE PORTER, Individually, and as Parents and Natural Guardians of ROBERT T. "Bo" PORTER, A Minor**<br>1160 ROCKWELL<br>XENIA, OH 45385<br><br>**Plaintiffs,**<br><br>vs.<br><br>**SMITHKLINE BEECHAM CORPORATION D/B/A, GLAXOSMITHKLINE,**<br>ONE FRANKLIN PLAZA<br>PHILADELPHIA, PA 19102-1225<br><br>And<br><br>**PFIZER, INC.,**<br><br>**Defendants.** | **COURT OF COMMON PLEAS**<br>**TRIAL DIVISION**<br>**PHILADELPHIA COUNTY**<br><br>**SEPTEMBER 2007 TERM**<br><br>**NO. : 03275**<br><br>**IN RE: PAXIL PREGNANCY CASES**<br><br>**JURY TRIAL DEMANDED** |

Case ID: 070903275

**CIVIL ACTION FIRST AMENDED SHORT - FORM COMPLAINT FOR PAXIL PREGNANCY CASES**

Pursuant to the Order by the Honorable Allan L. Tereshko, Philadelphia County Court of Common Pleas, the following Short Form Complaint and Supplemental Short Form are utilized in this mass tort action for cases alleging that a child suffers from a congenital birth defect, from Persistent Pulmonary Hypertension of the Newborn ("PPHN"), or other related or similar conditions, as a result of the child's mother ingesting the prescription medication Paxil, Paxil OS or Paxil CR ("Paxil") and/or Zoloft (sertraline hydrochloride) ("Zoloft") during her pregnancy. Plaintiff(s) select(s) and indicate(s) the causes of action raised in his/her/their case by checking off the appropriate spaces corresponding to the causes listed herein. In the event that a cause not listed herein is being raised, or where a claim requires, pursuant to Pennsylvania law, specific pleading or case-specific facts, Plaintiff(s) shall add and include said cause or said pleading or facts by way of submitting a Supplemental Short Form Complaint as approved by the Court's Case Management Order.

1. Robert T. Porter, child, a minor, by Katherine Porter and/or, Parent and Guardian, against SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK").

2. A. Minor Plaintiff / Decedent

| | |
|---|---|
| Name: | Robert T. Porter |
| Place of Birth | Peoria, IL |
| State of Residence: | Ohio |
| Date of Birth: | 03/06/2006 |
| Date of Death: | N/A |

B. Guardians for Minor Plaintiff:

| | |
|---|---|
| Name: | Katherine Porter and Robert Porter |
| State of Residence: | Ohio |

Relationship to
Minor Plaintiff: Mother and Father of Injured Child

C. Mother of Minor Plaintiff, Individually:
Name: Katherine Porter
State of Residence: Ohio

D. Father of Minor Plaintiff, Individually:
Name: Robert Porter
State of Residence: Ohio

E. Wrongful Death Beneficiaries and/or Personal Representative of Estate of Joey L. Davis, Minor Plaintiff.
Name: N/A
State of Residence: N/A
Name: N/A
State of Residence: N/A

3. Robert T. Porter's mother ingested the following drugs relevant to this action for the described period:

| | |
|---|---|
| Paxil | X |
| Dose (if known): | 25 mg |
| Zoloft | X |
| Dose (if known): | 50 mg |

4. The prescribing physician was: Sunny Lee, M.D.

5. Robert T. Porter was born with or developed the following condition(s): Omphalocele, PPHN, and other related injuries.

6. Katherine Porter and Robert Porter, an individuals residing in the state noted above and claim damages as a result of Robert T. Porter's mother's ingestion of Paxil and/or Zoloft during her pregnancy.

7. The following claims are asserted herein:

X Count One: Breach of Express Warranty

| | | |
|---|---|---|
| X | Count Two: | Breach of Implied Warranty |
| X | Count Three: | Fraud |
| X | Count Four: | Intentional Infliction of Emotional Distress |
| X | Count Five: | Loss of Consortium |
| X | Count Six: | Negligence |
| X | Count Seven: | Negligence Per Se |
| X | Count Eight: | Negligent Pharmacovigilance |
| X | Count Nine: | Failure to Warn |
| X | Count Ten: | Negligent Misrepresentation |
| X | Count Eleven: | Punitive Damages |
| X | Count Twelve: | Strict Products Liability |
| N/A | Count Thirteen: | Survival/Survivorship Action |
| X | Count Fourteen: | Violation of Consumer Act |
| N/A | Count Fifteen: | Wrongful Death |
| X | Count Sixteen: | Loss of Income |
| X | Count Seventeen: | Medical Expenses |
| X | Count Eighteen: | Design Defect |

Respectfully submitted,

**ARNOLD & ITKIN LLP**

BY: /s/

**Kurt B. Arnold, Esq.**
**Jason A. Itkin, Esq.**
**Noah M. Wexler, Esq.**
Pending *pro hac vice*
1401 McKinney Street, Ste 2550
Houston, Texas 77010
Telephone: 713-222-3800
Telecopier: 713-222-3850

Rosemary Pinto, Esq.
PA Bar #53114

Feldman & Pinto
1604 Locust Street, 2nd Floor
Philadelphia, PA 19103
Telephone: 215-546-2604
Telecopier: 215-546-9904
**ATTORNEYS FOR PLAINTIFFS**

**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the above and foregoing instrument has been forwarded to counsel of record, by the undersigned, pursuant to Pennsylvania Rules of Civil Procedure on the 14th day of June, 2012.

Joseph E. O'Neil
Mary Grace Maley
Carolyn McCormack
Lavin, O'Neil, Ricci, Cedrone & DiSipio
190 North Independence Mall West
6th & Race Streets
Philadelphia, PA 19106
Counsel for Defendants: GSK.

/s/ Rosemary Pinto
Rosemary Pinto

**Rosemary Pinto, Esq.**
PA Bar #53114
**FELDMAN & PINTO**
1604 Locust Street, 2nd Floor
Philadelphia, PA 19103
Tel: 215-546-2604
Fax: 215-546-9904

**ARNOLD & ITKIN LLP**
**Kurt B. Arnold**
**Jason A. Itkin**
**Alexander G. Dwyer**
Admitted *pro hac vice*
Texas State Bar No.: 24039117
1401 McKinney St., Suite 2550
Houston, Texas 77010
Tel: 713-222-3800
Fax: 713-222-3850
***Attorneys for Plaintiff***

**This is Not An Arbitration Case. An Assessment of Damages Is Required.**

| | |
|---|---|
| **ROBERT PORTER and KATHERINE PORTER, Individually, and as Parents and Natural Guardians of ROBERT T. "Bo" PORTER, A Minor** | **COURT OF COMMON PLEAS**<br>**TRIAL DIVISION**<br>**PHILADELPHIA COUNTY** |
| **Plaintiffs,** | **SEPTEMBER 2007 TERM** |
| vs. | **NO. : 03275** |
| **SMITHKLINE BEECHAM CORPORATION D/B/A, GLAXOSMITHKLINE,** | **IN RE: PAXIL PREGNANCY CASES** |
| and | **JURY TRIAL DEMANDED** |
| **PFIZER, INC.,** | |
| **Defendants.** | |

**SUPPLEMENT TO FIRST AMENDED SHORT–FORM COMPLAINT FOR PAXIL PREGNANCY CASES**

8. Pursuant to the Orders by the Honorable Allan L. Tereshko, Philadelphia County Court of Common Pleas, Plaintiff files the following Supplement to Short Form Complaint:

**INCORPORATION OF SHORT-FORM AND LONG-FORM COMPLAINTS**

9. Plaintiffs' paragraphs 1 through 7 (Short-Form Complaint, and amendments or supplements thereto) and the approved Long-Form Complaint are incorporated herein as if set forth in full.

**DEFENDANTS**

10. Plaintiffs incorporate by reference all the above referenced paragraphs as if set forth in full herein.

11. Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK") was and still is a corporation duly existing under and by virtue of the laws of the State of Pennsylvania with its principal place of business in Philadelphia, Pennsylvania. At all times hereinafter mentioned, GSK was, and still is, a pharmaceutical company involved in research, development, testing, manufacturing, production, promotion, distribution, and marketing of pharmaceuticals for distribution, sale, and use by the general public, including the drug Paxil (known generically as Paroxetine), an antidepressant, throughout the United States.

12. Defendant, Pfizer, Inc. ("Pfizer") was and still is a corporation duly existing under and by virtue of the laws of the State of Delaware with its principal place of business in the New York City, New York. Pfizer may be served with process by serving its registered agent: CT Corporation, 116 Pine Street, Suite 320, Harrisburg, PA 17101. At all

times hereinafter mentioned, Pfizer was, and still is, a pharmaceutical company involved in research, development, testing, manufacturing, production, promotion, distribution, and marketing of pharmaceuticals for distribution, sale, and use by the general public, including the drug Zoloft (sertraline hydrochloride) ("Zoloft") an antidepressant, throughout the United States.

**JURISDICTIONAL ALLEGATIONS**

13. Plaintiffs incorporate by reference all the above referenced paragraphs as if set forth in full herein.

14. Jurisdiction is proper because GSK is a Pennsylvania corporation. Venue is proper in this District Because GSK resides in this county for venue purposes and a substantial part of the events and omissions giving rise to Plaintiff's injuries occurred in this District. *See* Pa. R. C.P. 2179, as amended by 2003 Pennsylvania Court Order 8.

15. At all times material to this action, Defendant Pfizer and/or its predecessors in interest and/or its subsidiaries, regularly engaged in business in the Commonwealth of Pennsylvania and the County of Philadelphia, including advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packing, producing, promoting, processing, researching, selling, and testing of the pharmaceutical drug Zoloft. Defendant Pfizer carried on a continuous and systematic part of their business in Pennsylvania and in Philadelphia County. Furthermore, as Defendant Pfizer regularly solicited and transacted business, received substantial revenues from the Commonwealth of Pennsylvania, and/or distributed products in the Commonwealth of Pennsylvania and the City of Philadelphia, Defendant Pfizer is subject to suit in the Commonwealth of Pennsylvania. In addition, Defendant Pfizer

reasonably expected that Zoloft would be used or consumed in Pennsylvania and Philadelphia County. Furthermore, a part of the events and omissions giving rise to Plaintiffs' injuries occurred in this District.

16. This is an action for damages that exceed the sum of fifty thousand dollars ($50,000.00).

17. Plaintiffs have timely filed this lawsuit within the applicable statutory limitations period.

18. **No Basis for Removal.** There is no basis for removal of this case to federal court. Plaintiffs are not asserting a claim or right arising under the Constitution, treaties, or laws of the United States, thus, there is no federal question at issue pursuant to 28 U.S.C.§1441(b) and 28 U.S.C. §1331. There is no complete diversity of citizenship pursuant to 28 U.S.C. §1441(b) and 28 U.S.C. §1332(c), because GSK is a citizen of the Commonwealth of Pennsylvania. *See also Slater v. Hoffman-La Roche Inc.*, 771 F.Supp.2d 524 (E.D. Pa. 2011). Moreover, removal pursuant to 28 U.S.C. § 1332 upon the filing of a subsequent amended pleading more than one year after the filing of an initial pleading commencing the case, is expressly forbidden by the plain language of 28 U.S.C. § 1446(b). (*See* also, *Donato-Cook v. State Farm Fire & Cas. Co.*, CIV A 3:09-CV-0587, 2009 WL 2169168 (M.D. Pa. July 20, 2009)) (Defendant's notice of removal is time-barred by the one-year exception to removal in diversity cases pursuant to 28 U.S.C. § 1446(b).)

19. This matter was commenced more than one year ago, complete diversity is lacking and there is no federal question at issue. Any attempt to remove this matter would be improper and would provide grounds for sanctions.

## GENERAL ALLEGATIONS

20. Plaintiff incorporates by reference all the above paragraphs as if set forth in full herein.

21. The Mother Plaintiff took Zoloft as prescribed by her treating physician(s) while pregnant with Infant Plaintiff. *See* Exhibit A (Proof of Usage). The Mother Plaintiff continued to use Zoloft on the schedule and for the period of time prescribed by the Mother Plaintiff's physician(s).

22. The Mother Plaintiff took Zoloft as prescribed by her treating physician(s) while pregnant with the Infant Plaintiff. The Mother Plaintiff continued to use Zoloft on the schedule and for the period of time prescribed by the Mother Plaintiff's physician(s).

23. The Mother Plaintiff read the drug information and instructions that accompanied the Zoloft prescription prior to her taking Zoloft. The Mother Plaintiff trusted that serious conditions associated with Zoloft, such as congenital birth defects, would have been included and emphasized in the written drug information provided to her with her prescription. The Mother Plaintiff relied upon the fact that congenital birth defects and other serious pregnancy issues were not listed or emphasized on the Zoloft monograph and/or drug information as a basis to believe that Zoloft was safe for use during her pregnancy and would not cause congenital birth defects.

24. Despite the exercise of reasonable diligence in investigating the cause of the injuries, including consultations with her medical care providers, the Mother Plaintiff was not told that Zoloft could have caused the Infant Plaintiff's injuries. Nor did the Mother

Plaintiff see or read any information suggesting Zoloft caused the Infant Plaintiff's injuries until a date within the applicable statute of limitations for filing Plaintiffs' claims.

25. Had the Mother Plaintiff been adequately warned that Zoloft could cause congenital birth defects if ingested during pregnancy, she would not have taken the drug

26. When the Infant Plaintiff was born, he was suffering from life-threatening congenital defects.

27. The defects suffered by the Infant Plaintiff were a direct result of his mother's ingestion of Zoloft during her pregnancy in a manner and dosage recommended and prescribed by her doctor.

28. The drug "sertraline hydrochloride" was and is advertised, analyzed, assembled, compounded, designed, developed, distributed, formulated, inspected, labeled, manufactured, marketed, packed, produced, promoted, processed, researched, sold, and tested by Pfizer, its predecessors in interest and its subsidiaries, under the trade name Zoloft® and is a member of a class of drugs known as "selective serotonin reuptake inhibitors" or "SSRIs." Zoloft was first approved for use in the United States by the FDA in 1991 for the treatment of major depression in adults.

29. Under the FDA scheme, Pfizer, knew, as a New Drug Application applicant, that it must fully, truthfully and accurately disclose to the FDA data and information regarding a new drug's chemistry, proposed manufacturing process, proposed model labeling which includes warnings about risks and side effects, test results for the drug, results of animal studies, results of clinical studies and the drug's bioavailability, because the data and information would be relied upon by the medical community, physicians, Plaintiffs'

physicians, Plaintiffs and other foreseeable prescribers and users of Zoloft once the NDA was approved.

30. Under the FDA scheme, Pfizer had a duty to ensure its warnings to the medical community are and remain accurate and adequate, to conduct safety surveillance of adverse events for the drug, to report *any* data related to the safety and/or accuracy of the warnings and information disseminated regarding the drug, and to update the label when new safety information was obtained.

31. Prior to the Mother Plaintiff becoming pregnant, Pfizer knew or should have known that taking Zoloft during pregnancy posed risks to the developing fetus. Pfizer knew or should have known that Zoloft crosses the placenta, which could have important implications for the developing fetus.

32. Prior to the Mother Plaintiff becoming pregnant, Pfizer knew or should have known that children were being born with congenital birth defects, heart defects, PPHN, omphalocele and other similar conditions to women who took Zoloft during pregnancy.

33. Prior to the time that the Mother Plaintiff ingested Zoloft during her pregnancy, Pfizer knew of the dangerous birth defects associated with Zoloft's use during pregnancy from the preclinical studies and the subsequent published studies confirming these risks. Pfizer took no action to adequately warn or remedy the risks, but instead concealed, suppressed, and failed to disclose the dangers. Even in the face of the numerous published studies, Pfizer continues to fail to warn of these dangers through revised drug labeling.

34. Pfizer had access to this information and knew that congenital birth defects would result from the use of Zoloft by women who became pregnant and the fact that

physicians and the consumers such as the Mother Plaintiff herein did not fully understand the risks associated with Zoloft.

35. Pfizer failed to fully, truthfully and accurately disclose Zoloft data to the FDA, the Plaintiffs and the Mother Plaintiff's physicians, and as a result negligently, intentionally and fraudulently misled the medical community, physicians, the Mother Plaintiffs' physicians, and Plaintiffs about the risks to a fetus associated with the use of Zoloft during pregnancy.

36. Through the *Physicians' Desk Reference*, drug package inserts, patient information forms, counseling warnings, literature, marketing materials and other labeling information for Zoloft, Pfizer knowingly, intentionally and negligently disseminated incomplete, inaccurate, and/or misleading warnings and information about the true risks to a fetus when Zoloft is ingested during pregnancy, which misled the medical community, physicians and the Mother Plaintiff's physicians.

37. At all times material hereto, Pfizer knew or should have known that most physicians were not aware of or did not fully appreciate the seriousness of the congenital birth defect risks associated with use of Zoloft and that, consequently, there was a widespread tendency for physicians to prescribe Zoloft for use to women of childbearing potential. Consequently, Pfizer knew or should have known that the warnings and labels, including but not limited to, package inserts and the *Physician's Desk Reference* monograph for Zoloft, did not adequately inform physicians about the birth defects risks associated with Zoloft.

38. Pfizer failed to warn physicians and the Mother Plaintiff herein adequately about the congenital birth defect risks associated with Zoloft, despite the fact that Pfizer knew that physicians, the medical community, the Plaintiffs, and others similarly situated relied on Pfizer to disclose what it knew or should have known from a prudent review of the information that it possessed or to which it had access.

39. Because of the misleading information that Pfizer provided to physicians, the Plaintiffs and the FDA about the true congenital birth defect risks associated with the use of Pfizer and because of the failure of Pfizer to adequately inform physicians generally, including the Mother Plaintiff's physicians, about the true birth defect risks associated with the use of Zoloft the Mother Plaintiff's physicians never informed her of any congenital birth defects risks associated with Zoloft. Indeed, it is believed that Pfizer represented to physicians that Zoloft was safe for use by women of childbearing years and their unborn children.

40. Pfizer knew, or should have known, that the warnings, including but not limited to, the label and package insert for Zoloft did not disclose the true risks of birth defects from the use of Zoloft. Pfizer failed to use reasonable care to modify the warnings, including but not limited to, the label and package insert for Zoloft in order to warn physicians adequately about the true congenital birth defect risks from the use of Zoloft by women who became pregnant.

41. During the entire time Zoloft has been on the market in the United States, FDA regulations have required Pfizer to issue stronger warnings whenever there existed reasonable evidence of an association between a serious risk and Zoloft. The regulations

specifically state that a causal link need not have been proven to issue the new warnings. Further, the regulations explicitly allowed Pfizer to issue such a warning without prior FDA approval.

42. Thus, prior to the Mother Plaintiff's pregnancy, Pfizer had the knowledge, the means, and the duty to provide the medical community and the consuming public with a stronger warning regarding the association between Zoloft and congenital birth defects, heart defects, PPHN, and other related conditions, through all means necessary, including, but not limited to, labeling, continuing education, symposiums, posters, sales calls to doctors, advertisements, and promotional materials, etc. Pfizer breached this duty.

43. Despite having extensive knowledge of the extreme risks associated with the Zoloft, as well as the absolute duty to properly and adequately warn foreseeable users, Pfizer never approached the FDA to alter the label for Zoloft so that it properly and adequately warned of the risks of birth defects associated with the drug.

44. Pfizer failed to disclose adequately the increased risk of congenital birth defects of Zoloft to the medical community and the Plaintiffs. Pfizer was aware that its failure to disclose this information to the medical community and the Plaintiffs would result in serious injury and/or death to the children or unborn fetus of women who were prescribed Zoloft by a physician who was not aware of this information. By failing to disclose this information to the medical community and the Plaintiffs, Pfizer acted in willful, wanton and outrageous manner and with evil disregard of the rights of the Plaintiffs and this conduct caused serious and permanent injuries to the Plaintiffs.

45. Pfizer, its agents, servants and employees acting in the course and scope of their employment, negligently and carelessly breached their duties to the medical community, Plaintiffs' physicians, Plaintiffs and other foreseeable users similarly situated, which breaches of duty include, but are not limited to:

a. failing to ensure Zoloft warnings to the medical community, physicians, the Mother Plaintiff's physicians and Plaintiffs were accurate and adequate, despite having extensive knowledge of the risks associated with the drug;

b. failing in its obligation to provide the medical community, physicians, the Mother Plaintiff's physicians, and Plaintiffs with adequate and clinically relevant information, data and warnings regarding the adverse health risks associated with exposure to Zoloft, and/or that there existed safer and more or equally effective alternative drug products;

c. failing to conduct post market safety surveillance and report that information to the medical community, physicians, the Mother Plaintiff's physicians and Plaintiffs;

d. failing to include adequate warnings and/or provide adequate and clinically relevant information and data that would alert the medical community, physicians, Mother Plaintiff's physicians, and Plaintiffs to the dangerous risks of Zoloft;

e. failing to continually monitor, test, and analyze data regarding safety, efficacy and the prescribing practices for Zoloft;

f. failing to review all adverse drug event information (AER) and to report any information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Zoloft to the medical community, physicians, the Mother Plaintiff's physicians, and Plaintiffs;

g. failing to provide adequate post-marketing warnings and instructions after Pfizer knew or should have known of the significant risks of, among other things, congenital birth defects of Zoloft;

h. failing to periodically review all medical literature regarding Zoloft and failing to report data, regardless of the degree of significance, regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Zoloft;

i. failing to disclose the results of the testing and other information in its possession regarding the possibility that Zoloft can interfere with the proper development of an unborn fetus;

j. failing to warn adequately the medical community, physicians, the Mother Plaintiff's physicians, and Plaintiffs of the dangers of using Zoloft during pregnancy, including the risk of congenital birth defects;

k. representing that Zoloft was safe for use during pregnancy when, in fact, Pfizer knew or should have known that it was unsafe for this use and that Zoloft was associated with congenital birth defects;

l. promoting and marketing Zoloft for use with pregnant women, despite the fact that Pfizer knew or should have known that Zoloft was associated with an increased risk of congenital abnormalities;

m. promoting and marketing Zoloft as safe and effective for use with pregnant women when, in fact, it was unsafe;

n. promoting and marketing Zoloft for non-approved (off-label) uses and/or illegally over-promoting, marketing, advertising and selling Zoloft in a zealous and unreasonable way, without regard to the potential danger that it poses for an unborn fetus;

o. failing to independently monitor their sales of Zoloft and the medical literature, which would have alerted them to the fact that Zoloft was widely over-prescribed to women of childbearing potential as a result of inadequate warnings, including those in the package inserts and PDR monographs for Zoloft, and as a result of the over-promotion of the drug;

p. failing to act as a reasonably prudent drug manufacturer in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packing, producing, promoting, processing, researching, selling and testing of Zoloft; and/or

q. failing to perform adequate and necessary studies to determine and analyze the safety and risks associated with Zoloft use.

46. As a direct and proximate result of Pfizer's actions, Plaintiffs, and Mother Plaintiff's prescribing physicians, were unaware, and could not reasonably know, or through reasonable diligence could not have reasonably known, that Zoloft exposed the Plaintiffs to the risks and injuries alleged herein, and that those risks were the direct and proximate result of Pfizer's acts and omissions.

47. As a direct and proximate result of the conduct of Pfizer as described herein and as a result of the Mother Plaintiff's ingestion of Zoloft, the Infant Plaintiff suffers from physical injuries, some or all of which are permanent and/or may be fatal, and the Infant Plaintiff may suffer in the future from other diseases or conditions which have not yet been diagnosed. Further, the Infant Plaintiff has sustained in the past, and will sustain in the future, pain and suffering, mental anguish, embarrassment and humiliation, psychological injury, disability, disfigurement caused by the surgeries and procedures the Infant Plaintiff has already undergone, and the surgeries and procedures that Infant Plaintiff will need to undergo in the future, and the loss of enjoyment of the pleasures of life without the presence of congenital birth defects, and/or other related conditions, as well as past and future general and special damages, including past and future medical care and treatment, lost wages and lost earning capacity.

48. Infant Plaintiff's serious and permanent injuries were the foreseeable and proximate result of Pfizer's acts and/or omissions, including, but not limited to, dissemination of inaccurate, misleading, materially incomplete, false, and otherwise

inadequate information to the medical community, Mother Plaintiff's physicians, pharmacists and Plaintiffs.

49. As a direct and proximate result of the conduct of Pfizer as described herein, Parent Plaintiffs have suffered and will in the future continue to suffer medical, nursing, hospital, pharmacy, rehabilitative and related costs and expenses for the Infant Plaintiff's injuries and care, along with lost wages, lost earning capacity, economic losses, and other damages for which they are entitled to compensation. These injuries and damages were the foreseeable and proximate result of Pfizer's acts and/or omissions, including, but not limited to, dissemination of inaccurate, misleading, materially incomplete, false, and otherwise inadequate information to the medical community, Mother Plaintiff's physicians, pharmacists and Plaintiffs.

50. The Parent Plaintiffs, as result of the Mother Plaintiff's ingestion of Zoloft and as a direct and proximate result of the conduct of Pfizer described herein, have suffered, and will suffer in the future, great emotional pain, mental anguish and other serious injury and loss, including loss of consortium, services, support, companionship, society, love and affection. These injuries and damages were the foreseeable and proximate result of Pfizer's acts and/or omissions, including, but not limited to, dissemination of inaccurate, misleading, materially incomplete, false, and otherwise inadequate information to the medical community, Mother Plaintiff's physicians, pharmacists and Plaintiffs.

51. Pfizer is liable to the Plaintiffs for all general, special and punitive damages, as well as delay damages, and other relief to which they are entitled to by law.

**DISCOVERY RULE, TOLLING AND FRAUDULENT CONCEALMENT**

52. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

53. Plaintiffs assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, fraudulent concealment, and/or minority tolling.

54. Plaintiffs plead that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiffs had been injured, the cause of the injury, and the tortuous nature of the wrongdoing that caused the injury.

55. Despite diligent investigation by Plaintiffs into the cause of their injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages, and their relationship to Zoloft was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiffs' claims. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable statutory limitations period.

56. The running of the statute of limitations in this cause is tolled due to equitable tolling. Pfizer is estopped from asserting a statute of limitations defense due to Pfizer's fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiffs and Plaintiff's physicians and pharmacists of the true risks associated with taking Zoloft. As a result of Pfizer's fraudulent concealment, Plaintiffs and Plaintiff's prescribing

physicians and pharmacists were unaware, and could not have known or have learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of Pfizer.

57. The running of the statute of limitations in this cause may be tolled due to the pendency of a class action proceeding against one or more of the Defendants herein. Class Action tolling is proper where Plaintiffs are members of an asserted class and the claims asserted in the class action proceeding are the same as the claims asserted in this action.

58. The statute of limitations is tolled due to the minority of the Plaintiff. Plaintiff was a minor at the time Plaintiff ingested Zoloft. This action was filed within the applicable statutory period after Plaintiff achieved the age of majority. Ohio Rev. Code Ann. § 2305.16 and § 2305.10.

59. Defendants are estopped from asserting a statute of limitations defense because all Defendants fraudulently concealed from Plaintiffs the nature of Plaintiffs' injury and the connection between the injury and Defendants' tortious conduct.

## CLAIMS FOR RELIEF

60. The Plaintiffs set forth the following statements and claims in the alternative such that the sufficiency of this Complaint shall not be defeated by an inconsistency or insufficiency (if any) among any one or more of the alternative statements or claims.

### COUNT ONE – BREACH OF EXPRESS WARRANTIES
*(As Against Pfizer)*

60. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

61. Pfizer is liable to Plaintiffs under state common law and/or the applicable state Product Liability Acts for the breach of express warranties of Zoloft.

62. At all times hereinafter mentioned, upon information and belief, Pfizer, by directly and indirectly advertising, marketing, and promoting Zoloft for the treatment of women, including women of childbearing potential and pregnant women, and by placing Zoloft in the stream of commerce knowing that Zoloft would be prescribed to pregnant women in reliance upon the representations or omissions of Pfizer, expressly warranted to all foreseeable users of Zoloft, including the Mother Plaintiff and the Mother Plaintiff's physicians, that Zoloft was safe and effective for the treatment of women during pregnancy and without significant risk to the fetus.

63. Pfizer impliedly warranted in manufacturing, distributing, selling, advertising, marketing, and promoting Zoloft to all foreseeable users, including the Mother Plaintiff and the Mother Plaintiff's physicians, that Zoloft was safe and effective for the purposes for which it had been placed in the stream of commerce by Pfizer, including for the treatment of pregnant women, and that Zoloft was reasonably safe, proper, merchantable, and fit for its intended purpose, including for the treatment of pregnant women and without significant risk to the fetus.

64. At all times relevant hereto, Plaintiffs and the Mother Plaintiff's physicians relied upon the aforesaid express warranties by Pfizer.

65. The Mother Plaintiff's use of Zoloft, and the Mother Plaintiff's physicians' prescribing of Zoloft was consistent with the purposes for which Pfizer directly and indirectly advertised, marketed, and promoted Zoloft, and the Mother Plaintiff's use of Zoloft, and the Mother Plaintiff's physicians' prescribing of Zoloft was reasonably contemplated, intended, and foreseen by Pfizer at the time of the distribution and sale of Zoloft by Pfizer, and, therefore, the Mother Plaintiff's use of Zoloft was within the scope of the above-described express warranties.

66. Pfizer breached the aforesaid express warranties because Zoloft was not safe and effective for the treatment of women during pregnancy because it exposed the developing fetus to a significant risk of serious injury, and because the Mother Plaintiff's use of Zoloft for treatment during her pregnancy caused the Infant Plaintiff's injuries.

67. As a direct and proximate result of Pfizer's breach of express warranties, Plaintiffs suffered injuries and damages, as set forth herein.

**WHEREFORE**, for the above reasons, Plaintiffs demand judgment in their favor and against Pfizer for an amount in excess of $50,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

## COUNT TWO - BREACH OF IMPLIED WARRANTIES

*(As Against Pfizer)*

68. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

69. Pfizer is liable to Plaintiffs under state common law and/or the applicable state Product Liability Acts for the breach of implied warranties of Zoloft.